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Presidential Documents

Title 3—

The President

Notice of June 21, 2016

Continuation of the National Emergency With Respect to North Korea

On June 26, 2008, by Executive Order 13466, the President declared a national emergency with respect to North Korea pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the existence and risk of proliferation of weapons-usable fissile material on the Korean Peninsula. The President also found that it was necessary to maintain certain restrictions with respect to North Korea that would otherwise have been lifted pursuant to Proclamation 8271 of June 26, 2008, which terminated the exercise of authorities under the Trading With the Enemy Act (50 U.S.C. App. 1–44) with respect to North Korea.

On August 30, 2010, I signed Executive Order 13551, which expanded the scope of the national emergency declared in Executive Order 13466 to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States posed by the continued actions and policies of the Government of North Korea, manifested by its unprovoked attack that resulted in the sinking of the Republic of Korea Navy ship *Cheonan* and the deaths of 46 sailors in March 2010; its announced test of a nuclear device and its missile launches in 2009; its actions in violation of United Nations Security Council Resolutions 1718 and 1874, including the procurement of luxury goods; and its illicit and deceptive activities in international markets through which it obtains financial and other support, including money laundering, the counterfeiting of goods and currency, bulk cash smuggling, and narcotics trafficking, which destabilize the Korean Peninsula and imperil U.S. Armed Forces, allies, and trading partners in the region.

On April 18, 2011, I signed Executive Order 13570 to take additional steps to address the national emergency declared in Executive Order 13466 and expanded in Executive Order 13551 that will ensure the implementation of the import restrictions contained in United Nations Security Council Resolutions 1718 and 1874 and complement the import restrictions provided for in the Arms Export Control Act (22 U.S.C. 2751 *et seq.*).

On January 2, 2015, I signed Executive Order 13687 to take further steps with respect to the national emergency declared in Executive Order 13466, as expanded in Executive Order 13551, and addressed further in Executive Order 13570, to address the threat to the national security, foreign policy, and economy of the United States constituted by the provocative, destabilizing, and repressive actions and policies of the Government of North Korea, including its destructive, coercive cyber-related actions during November and December 2014, actions in violation of United Nations Security Council Resolutions 1718, 1874, 2087, and 2094, and commission of serious human rights abuses.

On March 15, 2016, I signed Executive Order 13722 to take additional steps with respect to the national emergency declared in Executive Order 13466, as modified in scope and relied upon for additional steps in subsequent Executive Orders, to address the Government of North Korea's continuing pursuit of its nuclear and missile programs, as evidenced by its February 7, 2016, launch using ballistic missile technology and its January

6, 2016, nuclear test in violation of its obligations pursuant to numerous United Nations Security Council Resolutions and in contravention of its commitments under the September 19, 2005, Joint Statement of the Six-Party Talks, that increasingly imperils the United States and its allies. Executive Order 13722 also implements certain multilateral sanctions imposed under United Nations Security Council Resolution 2270.

The existence and risk of proliferation of weapons-usable fissile material on the Korean Peninsula and the actions and policies of the Government of North Korea continue to pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States. For this reason, the national emergency declared in Executive Order 13466, expanded in scope in Executive Order 13551, addressed further in Executive Order 13570, further expanded in scope in Executive Order 13687, and under which additional steps were taken in Executive Order 13722 of March 15, 2016, and the measures taken to deal with that national emergency, must continue in effect beyond June 26, 2016. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to North Korea declared in Executive Order 13466.

This notice shall be published in the *Federal Register* and transmitted to the Congress.

THE WHITE HOUSE,
June 21, 2016.

[FR Doc. 2016–15036
Filed 6–22–16; 8:45 am]
Billing code 3295–F6–P

Presidential Documents

Notice of June 21, 2016

Continuation of the National Emergency With Respect to the Western Balkans

On June 26, 2001, by Executive Order 13219, the President declared a national emergency with respect to the Western Balkans, pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706), to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the actions of persons engaged in, or assisting, sponsoring, or supporting (i) extremist violence in the Republic of Macedonia and elsewhere in the Western Balkans region, or (ii) acts obstructing implementation of the Dayton Accords in Bosnia or United Nations Security Council Resolution 1244 of June 10, 1999, in Kosovo. The President subsequently amended that order in Executive Order 13304 of May 28, 2003, to take additional steps with respect to acts obstructing implementation of the Ohrid Framework Agreement of 2001 relating to Macedonia.

The actions of persons threatening the peace and international stabilization efforts in the Western Balkans, including acts of extremist violence and obstructionist activity, continue to pose an unusual and extraordinary threat to the national security and foreign policy of the United States. For this reason, the national emergency declared on June 26, 2001, and the measures adopted on that date and thereafter to deal with that emergency, must continue in effect beyond June 26, 2016. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to the Western Balkans declared in Executive Order 13219.

This notice shall be published in the *Federal Register* and transmitted to the Congress.

THE WHITE HOUSE,
June 21, 2016.

[FR Doc. 2016–15041
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Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 52

[Document Number AMS–FV–14–0087, FV–16–329]

United States Standards for Grades of Processed Raisins

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: The Agricultural Marketing Service (AMS) of the U.S. Department of Agriculture (USDA) is revising the United States Standards for Grades of Processed Raisins by removing five references to the term "midget" throughout the standards. These changes will modernize and clarify the standards by removing dual terminology for the same requirement.

DATES: Effective July 25, 2016.

FOR FURTHER INFORMATION CONTACT: Lindsay Mitchell at Standardization Branch, Specialty Crops Inspection Division, Specialty Crops Program, Agricultural Marketing Service, U.S. Department of Agriculture, National Training and Development Center, Riverside Business Park, 100 Riverside Parkway, Suite 101, Fredericksburg, VA 22406, or at phone (540) 361–1120; fax (540) 361–1199; or, email *Lindsay.Mitchell@ams.usda.gov.* Copies of the proposed U.S. Standards for Grades of Processed Raisins are available on the Internet at *http://www.regulations.gov.* The current U.S. Standards for Grades of Processed Raisins are available on the Specialty Crops Inspection Division Web site at *http://www.ams.usda.gov/grades-standards.*

SUPPLEMENTARY INFORMATION: The changes remove the dual nomenclature terminology "small or midget" for the same requirement from the U.S. Standards for Grades of Processed Raisins. These revisions also affect the grade requirements under the marketing order, 7 CFR parts 989, issued under the Agricultural Marketing Agreement Act of 1937 (7 U.S.C. 601–674) and applicable imports.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health and safety effects, and distributive impacts and equity. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

Executive Order 13175

This action has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation would not have substantial and direct effects on Tribal governments and would not have significant Tribal implications.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. There are no administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this rule.

Regulatory Flexibility Act and Paperwork Reduction Act

Pursuant to the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of these revisions on small entities, and prepared the following final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions so small businesses will not be unduly or disproportionately burdened. Marketing orders issued under the Act, and the rules issued thereunder, are unique in that they are brought about through group action of small entities acting on their own behalf.

There are approximately 3,000 California raisin producers and 28 handlers subject to regulation under the marketing order. The Small Business Administration defines small agricultural producers as those with annual receipts less than $750,000, and defines small agricultural service firms as those with annual receipts less than $7,500,000 (13 CFR 121.201).

Based on shipment data and other information provided by the Raisin Administrative Committee (RAC), which administers the Federal marketing order for raisins produced from grapes grown in California, most producers and approximately 18 handlers of California raisins may be classified as small entities. The RAC represents the entire California raisin industry; no other state produces raisins commercially. This action should not have any impact on handlers' or growers' benefits or costs.

The action will clarify AMS grade standards by eliminating the use of the term "midget" and consistently using the term "small" for raisins graded in that category. The industry has used the two terms interchangeably for years. The proposed grade standards will be applied uniformly by all handlers.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this rule will not change the information collection and recordkeeping requirements previously approved, and will impose no additional reporting or recordkeeping burden on domestic producers, first handlers, and importers of processed raisins.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule. The rule will impact marketing programs that regulate the handling of processed raisins under 7 CFR part 989. Raisins under a marketing order must meet certain requirements set forth in the grade standards. In addition, raisins are subject to section 8e import requirements under the Agricultural Marketing Act of 1937, as amended (7 U.S.C. 601–674), which requires that imported raisins meet grade, size, and quality under the applicable marketing order (7 CFR part 999).

Background

AMS continually reviews all fruit and vegetable grade standards to ensure their usefulness to the industry, and to modernize language and remove duplicative terminology. On May 13, 2013, AMS received a petition from the Little People of America stating that they "are trying to raise awareness around and eliminate the use of the word midget." The petition further stated that, "Though the use of the word midget by the USDA when classifying certain food products is benign, Little People of America, and the dwarfism community, hopes that the USDA would consider phasing out the term midget."

AMS determined that the processed raisin grade standard contained "small or midget" terminology for the same requirement. Before developing these proposed revisions, AMS solicited comments and suggestions about the grade standards from the RAC, which represents the entire California raisin industry. On August 14, 2014, the RAC approved the removal of the term midget from the standards.

On August 21, 2015, AMS published a Proposed Rule in the **Federal Register** (80 FR 50803) soliciting comments on removing five references to the term "midget" from the standards. Eight comments were submitted by October 20, 2015, the closing date of the public comment period. Five of the eight comments fully supported the revisions; three did not.

Five commenters, one of which represents the dwarfism community, fully support the revisions. Four of them believe the issue is not about political correctness, but, rather, is a matter of common decency and respect. They also believe eliminating the term "midget" from USDA documents will raise awareness that the term is socially unacceptable. In addition, one commenter believes it is redundant to have two names for the same size category. All agree the term "midget" is unneeded and should be removed.

Two of the three opposing commenters believe the USDA should address more important issues and not concern themselves with being "politically correct." The third stated that even though they understand the concern of Little People of America, they believe addressing the issue is unnecessary, since, in their purchasing experience, they have never encountered raisins identified by size. The USDA and RAC support the Little People of America in the removal of the term "midget" from the raisin standards as a matter of common decency, that there is limited use of the term by industry, and because it is redundant as there is also the term "small" for the size category. No changes have been made to the rule based on the comments.

Based on the information gathered, AMS is removing five references to the term "midget" in the following sections: 52.1845(b) and (c), 52.1850(a)(2) and (a)(3), and Table I. The revisions will modernize and help clarify the language of the standard by removing dual terminology for the same requirement.

List of Subjects in 7 CFR Part 52

Food grades and standards, Food labeling, Frozen foods, Fruit juices, Fruits, Reporting and recordkeeping requirements, Vegetables.

For reasons set forth in the preamble, 7 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 7 U.S.C. 1621–1627.

■ 2. In § 52.1845, paragraphs (b) and (c) are revised to read as follows:

§ 52.1845 Sizes of seedless raisins.

* * * * *

(b) *Small* size raisins means that 95 percent, by weight, of all the raisins will pass through round perforations $^{24}/_{64}$-inch in diameter, and not less than 70 percent, by weight, of all raisins will pass through round perforations $^{22}/_{64}$-inch in diameter.

(c) *Mixed* size raisins means a mixture that does not meet either the requirements for "select" size or for "small" size.

■ 3. In § 52.1846, Table I is amended under the heading "Substandard development and undeveloped" by removing the entry for "Small (Midget) size" and adding in its place an entry for "Small size" to read as follows:

§ 52.1846 Grades of seedless raisins.

* * * * *

TABLE I—ALLOWANCES FOR DEFECTS IN TYPE I, SEEDLESS RAISINS AND TYPE II, GOLDEN SEEDLESS RAISINS

Defects	U.S. Grade A	U.S. Grade B	U.S. Grade C
* * * * *		*	*
Substandard development and undeveloped	Total	Total	Total
* * * * *		*	*
Small size	2	3	5
* * * * *		*	*

■ 4. In § 52.1850, paragraphs (a)(2) and (3) are revised to read as follows:

§ 52.1850 Sizes of raisins with seeds—except layer or cluster.

* * * * *

(a) * * *

(2) *Small* size raisins means that all of the raisins will pass through round perforations $^{34}/_{64}$-inch in diameter and not less than 90 percent, by weight, of all the raisins will pass through round perforations $^{22}/_{64}$-inch in diameter.

(3) *Mixed* size raisins means a mixture does not meet either the requirements for "select" size or for "small" size.

* * * * *

Dated: June 17, 2016.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2016–14821 Filed 6–22–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 925

[Doc. No. AMS–SC–15–0077; SC16–925–1 FR]

Grapes Grown in a Designated Area of Southeastern California; Increased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule implements a recommendation from the California Desert Grape Administrative Committee (Committee) for an increase of the assessment rate established for the 2016 and subsequent fiscal periods from $0.0250 to $0.0300 per 18-pound lug of grapes handled under the marketing order (order). The Committee locally administers the order, and is comprised of producers and handlers of grapes grown and handled in a designated area of southeastern California. Assessments upon grape handlers are used by the Committee to fund reasonable and necessary expenses of the program. The fiscal period began on January 1 and ends December 31. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Effective June 24, 2016.

FOR FURTHER INFORMATION CONTACT: Kathie Notoro, Marketing Specialist, or Jeffrey Smutny, Regional Director, California Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 487–5901, Fax: (559) 487–5906, or Email: *Kathie.Notoro@ams.usda.gov* or *Jeffrey.Smutny@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Antoinette Carter, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Antoinette.Carter@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Order No. 925, as amended (7 CFR part 925), regulating the handling of grapes grown in a designated area of southeastern California, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the "Act."

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 12866, 13563, and 13175.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the marketing order now in effect, grape handlers in a designated area of southeastern California are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the assessment rate as issued herein will be applicable to all assessable grapes beginning on January 1, 2016, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule increases the assessment rate established for the Committee for the 2016 and subsequent fiscal periods from $0.0250 to $0.0300 per 18-pound lug of grapes handled.

The grape marketing order provides authority for the Committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the Committee are producers and handlers of grapes grown in a designated area of southeastern California. They are familiar with the Committee's needs and with the costs of goods and services in their local area and are thus in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2015 and subsequent fiscal periods, the Committee recommended, and the USDA approved, an assessment rate that would continue in effect from fiscal period to fiscal period unless modified, suspended, or terminated by USDA based upon recommendation and information submitted by the Committee or other information available to USDA.

The Committee met on November 12, 2015, and unanimously recommended 2016 expenditures of $143,500, a contingency reserve fund of $6,500, and an assessment rate of $0.0300 per 18-pound lug of grapes handled. In comparison, last year's budgeted expenditures were $135,500. The Committee recommended a crop estimate of 5 million, 18-pound lugs, which is lower than the 5.8 million, 18-pound lugs handled last year. The Committee also recommended carrying over a financial reserve of $47,500, which would increase to $54,000, at the end of the fiscal period. The assessment rate of $0.0300 per 18-pound lug of grapes handled recommended by the Committee is $0.0050 higher than the $0.0250 rate currently in effect. The higher assessment rate, applied to shipments of 5 million, 18-pound lugs, is expected to generate $150,000 in revenue and be sufficient to cover anticipated expenses.

The major expenditures recommended by the Committee for the 2016 fiscal period include $28,500 for research, $20,080 for office expenses, $56,500 for management and compliance expenses, $25,000 for consultation services, and $6,500 for a contingency reserve. The $28,500 research project is a continuation of a vine study in progress by the University of California, Riverside.

In comparison, major expenditures for the 2015 fiscal period included $15,500 for research, $17,000 for general office expenses, $62,750 for management and compliance expenses, $25,000 for consultation services, and $9,500 for a contingency reserve. Overall 2016 expenditures include a decrease in management and compliance expenses, and increases in office and research expenses.

The assessment rate recommended by the Committee was derived by evaluating several factors, including estimated shipments for the 2016 season, proposed expenses, and the level of available financial reserves. The Committee determined that the $0.0300 assessment rate should generate $150,000 in revenue to cover the budgeted expenses of $143,500, and a contingency reserve fund of $6,500.

Reserve funds by the end of 2016 are projected to be $54,000. The reserve would be well within the reserve amount authorized under the order. Section 925.41 of the order permits the Committee to maintain approximately one fiscal period's expenses in reserve.

The assessment rate established in this rule will continue in effect indefinitely unless modified, suspended, or terminated by USDA based upon a recommendation and information submitted by the Committee or other available information.

Although this assessment rate will be in effect for an indefinite period, the Committee will continue to meet prior to or during each fiscal period to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA will evaluate the Committee's recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking will be undertaken as necessary. The Committee's 2016 budget and those for subsequent fiscal periods will be reviewed and, as appropriate, approved by USDA.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 12 handlers of southeastern California grapes who are subject to regulation under the marketing order and about 38 grape producers in the production area. Small agricultural service firms are defined by the Small Business Administration as those having annual receipts of less than $7,500,000, and small agricultural producers are defined as those whose annual receipts are less than $750,000(13 CFR 121.201).

Seven of the 12 handlers subject to regulation have annual grape sales of less than $7,500,000, according to USDA Market News Service and Committee data. In addition, information from the Committee and USDA's Market News indicates that at least nine of the 38 producers have annual receipts of less than $750,000. Based on the foregoing, it may be concluded that slightly more than half of the grape handlers and a minority of the grape producers could be classified as small entities.

This rule increases the assessment rate established for the Committee and collected from handlers for the 2016 and subsequent fiscal periods from $0.0250 to $0.0300 per 18-pound lug of grapes. The Committee unanimously recommended 2016 expenditures of $143,500, a contingency reserve fund of $6,500, and an assessment rate of $0.0300 per 18-pound lug of grapes handled. The assessment rate of $0.0300 is $0.0050 higher than the 2015 rate. The quantity of assessable grapes for the 2016 season is estimated at 5 million, 18-pound lugs. Thus, the $0.0300 rate should generate $150,000 in income. In addition, reserve funds at the end of the year are projected to be $54,000, which is well within the order's limitation of approximately one fiscal period's expenses.

The major expenditures recommended by the Committee for the 2016 fiscal period include $28,500 for research, $20,080 for general office expenses, $56,500 for management and compliance expenses, $25,000 for consultation services and $6,500 for the contingency reserve.

In comparison, major expenditures for the 2015 fiscal period included $15,500 for research, $17,000 for general office expenses, $62,750 for management and compliance expenses, $25,000 for consultation services, and $9,500 for a contingency reserve. Overall 2016 expenditures include a decrease in management and compliance expenses, and increases in general office expenses, and research expenses.

Prior to arriving at this budget and assessment rate, a subcommittee met to discuss this matter for the purpose of making a recommendation to the Committee. The Committee considered alternative expenditures and assessment rates, to include not increasing the $0.0250 assessment rate. Based on a crop estimate of 5 million, 18-pound lugs, the Committee ultimately determined that increasing the assessment rate to $0.0300 would generate sufficient funds to cover budgeted expenses. Reserve funds at the end of the 2016 fiscal period are projected to be $54,000. This amount is well within the amount authorized under the order.

A review of historical crop and price information, as well as preliminary information pertaining to the upcoming fiscal period, indicates that the shipping point price for the 2015 season averaged about $22.75 per 18-pound lug of California desert grapes handled. If the 2016 price is similar to the 2015 price, estimated assessment revenue as a percentage of total estimated handler revenue will be 0.13 percent for the 2016 season ($0.0300 divided by $22.75 per 18-pound lug).

This action increases the assessment obligation imposed on handlers. While assessments impose some additional costs on handlers, the costs are minimal and uniform on all handlers. However, these costs are offset by the benefits derived from the operation of the marketing order. In addition, the Committee's meeting was widely publicized throughout the grape production area and all interested persons were invited to attend and participate in Committee deliberations on all issues. Like all Committee meetings, the November 12, 2015, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0189, Generic Fruit Crops. No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

This rule imposes no additional reporting or recordkeeping requirements on either small or large California grape handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. As noted in the initial regulatory flexibility analysis, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this final rule.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

A proposed rule concerning this action was published in the **Federal Register** on March 10, 2016 (81 FR 12605). Copies of the proposed rule were also provided to all grape handlers. Finally, the proposal was made available through the internet by USDA and the office of the Federal Register. A 15-day comment period ending March 25, 2016, was provided for interested persons to respond to the proposal. No comments were received.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Antoinette Carter at the previously-mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule, as herein set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) The 2016 fiscal period began on January 1, 2016, and the marketing order requires that the rate of assessment for each fiscal period apply to all assessable grapes handled during such fiscal period; (2) the Committee needs to have sufficient funds to pay its expenses, which are incurred on a continuous basis; and (3) handlers are aware of this action, which was unanimously recommended by the Committee at a public meeting and is similar to other assessment rate actions issued in past years. Also, a 15-day comment period was provided for in the proposed rule and no comments were received.

List of Subjects in 7 CFR Part 925

Grapes, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 925 is amended as follows:

PART 925—GRAPES GROWN IN A DESIGNATED AREA OF SOUTHEASTERN CALIFORNIA

■ 1. The authority citation for 7 CFR part 925 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 925.215 is revised to read as follows:

§ 925.215 Assessment rate.

On and after January 1, 2016, an assessment rate of $0.0300 per 18-pound lug is established for grapes grown in a designated area of southeastern California.

Dated: June 17, 2016.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2016–14824 Filed 6–22–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 748

[Docket No. 160303186–6186–01]

RIN 0694–AG91

Amendments to Existing Validated End-User Authorization in the People's Republic of China: Advanced Micro Devices, Inc.

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) to revise the existing Validated End-User (VEU) list for the People's Republic of China by updating the list of eligible items and destinations (facilities) for VEU Advanced Micro Devices, Inc. (AMD). Specifically, BIS amends Supplement No. 7 to part 748 of the EAR to remove an existing "eligible destination" (facility); add a building to an existing address at one of AMD's already approved facilities to which eligible items may be exported, reexported or transferred (in-country); and reflect the recent removal of an existing "eligible item" from the Commerce Control List (CCL).

DATES: This rule is effective June 23, 2016.

FOR FURTHER INFORMATION CONTACT: Chair, End-User Review Committee, Office of the Assistant Secretary, Export Administration, Bureau of Industry and Security, U.S. Department of Commerce, Phone: 202–482–5991; Email: *ERC@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

Authorization Validated End-User

Validated End-Users (VEUs) are designated entities located in eligible destinations to which eligible items may be exported, reexported, or transferred (in-country) under a general authorization instead of a license. The names of the VEUs, as well as the dates they were so designated, and their respective eligible destinations (facilities) and items are identified in Supplement No. 7 to part 748 of the EAR. Under the terms described in that supplement, VEUs may obtain eligible items without an export license from BIS, in conformity with section 748.15 of the EAR. Eligible items vary between VEUs and may include commodities, software, and technology, except those controlled for missile technology or crime control reasons on the Commerce Control List (CCL) (part 774 of the EAR).

VEUs are reviewed and approved by the U.S. Government in accordance with the provisions of section 748.15 and Supplement Nos. 8 and 9 to part 748 of the EAR. The End-User Review Committee (ERC), composed of representatives from the Departments of State, Defense, Energy, Commerce, and other agencies as appropriate, is responsible for administering the VEU program. BIS amended the EAR in a final rule published on June 19, 2007 (72 FR 33646), to create Authorization VEU.

Amendments to Existing VEU Authorization for Advanced Micro Devices, Inc. (AMD) in the People's Republic of China

Revision to the List of "Eligible Destinations" and "Eligible Items" for AMD

In this final rule, BIS amends Supplement No. 7 to part 748 to revise AMD's VEU authorization. Specifically, in this rule BIS removes one of AMD's existing eligible destinations (facilities). Also, in this rule, BIS adds a building to an existing address at one of AMD's facilities already approved under Authorization VEU, to which the company's eligible items may be exported, reexported or transferred (in-country) in the People's Republic of China (PRC) under the authorization. Finally, in this rule, BIS removes Export Control Classification Number (ECCN) 4D002 from the list of AMD's eligible items to reflect the removal of that item from the CCL by 80 FR 29432 (May 21, 2015). The amendments to the eligible destinations (facilities) are in response to a request from AMD, while the amendment to the eligible items list reflects the recent removal of that ECCN from the CCL. All amendments were approved by the ERC. The revisions are as follows:

Removal of AMD's Eligible Destination (Facility)

AMD Technologies (China) Co., Ltd., No. 88, Su Tong Road, Suzhou, China 215021.

Revision and Update of Address for One of AMD's Eligible Destinations (Facilities)

Current Address: Advanced Micro Devices (Shanghai) Co., Ltd., Buildings 46, 47, 48 & 49, River Front Harbor, Zhangjiang Hi-Tech Park, 1387 Zhangdong Rd., Pudong, Shanghai, China 201203

New Address: Advanced Micro Devices (Shanghai) Co., Ltd., Buildings 33 (Unit 1), 46, 47, 48 & 49, River Front Harbor, Zhangjiang Hi-Tech Park, No. 1387 Zhang Dong Road, Pudong District, Shanghai, China 201203

Removal of AMD's Eligible Item: ECCN 4D002

With this revision, AMD's "Eligible Items" are as follows: 3D002, 3D003, 3E001 (limited to "technology" for items classified under 3C002 and 3C004 and "technology" for use during the International Technology Roadmap for Semiconductors (ITRS) process for items classified under ECCNs 3B001 and 3B002), 3E002 (limited to "technology" for use during the ITRS process for items classified under ECCNs 3B001 and 3B002), 3E003.e (limited to the "development" and "production" of integrated circuits for commercial applications), 4D001 and 4E001 (limited to the "development" of products under ECCN 4A003.

Export Administration Act

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013) and as extended by the Notice of August 7, 2015, 80 FR 48233 (August 11, 2015), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. This rule involves collections previously approved by the Office of Management and Budget (OMB) under Control Number 0694–0088, "Multi-Purpose Application," which carries a burden hour estimate of 43.8 minutes to prepare and submit form BIS–748; and for recordkeeping, reporting and review requirements in connection with Authorization VEU, which carries an estimated burden of 30 minutes per submission. This rule is expected to result in a decrease in license applications submitted to BIS. Total burden hours associated with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA) and OMB Control Number 0694–0088 are not expected to increase significantly as a result of this rule. Notwithstanding any other provisions of law, no person is required to respond to, nor be subject to a penalty for failure to comply with a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

3. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

4. Pursuant to the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), BIS finds good cause to waive requirements that this rule be subject to notice and the opportunity for public comment because they are unnecessary. In determining whether to grant VEU designations, a committee of U.S. Government agencies evaluates information about and commitments made by candidate companies, the nature and terms of which are set forth in 15 CFR part 748, Supplement No. 8. The criteria for evaluation by the committee are set forth in 15 CFR 748.15(a)(2). The information, commitments, and criteria for this extensive review were all established through the notice of proposed rulemaking and public comment process (71 FR 38313 (July 6, 2006) (proposed rule), and 72 FR 33646 (June 19, 2007) (final rule)). Given the similarities between the authorizations provided under the VEU program and export licenses (as discussed further below), the publication of this information does not establish new policy. In publishing this final rule, BIS amends the authorization for an existing eligible VEU to remove an eligible destination (facility), revise an existing eligible destination (facility) to add a building, and remove an eligible item no longer listed on the CCL. These changes have been made within the established regulatory framework of the VEU program. Further, this rule does not abridge the rights of the public or eliminate the public's option to export under any of the forms of authorization set forth in the EAR.

Publication of this rule in other than final form is unnecessary because the authorizations granted in the rule are consistent with the authorizations granted to exporters for individual licenses (and amendments or revisions thereof), which do not undergo public review. In addition, as with license applications, VEU authorization applications contain confidential business information, which is necessary for the extensive review conducted by the U.S. Government in assessing such applications. This information is extensively reviewed according to the criteria for VEU authorizations, as set out in 15 CFR 748.15(a)(2). Additionally, just as license applications are reviewed through an interagency review process, the authorizations granted under the VEU program involve interagency deliberation and result from review of public and non-public sources, including licensing data, and the measurement of such information against the VEU authorization criteria. Given the nature of the review, and in light of the parallels between the VEU application review process and the review of license applications, public comment on this authorization and subsequent amendments prior to publication is unnecessary. Moreover, because, as noted above, the criteria and process for authorizing and administering VEUs were developed with public comments, allowing additional public comment on this amendment to individual VEU authorizations, which was determined according to those criteria, is unnecessary.

Section 553(d) of the APA generally provides that rules may not take effect earlier than thirty (30) days after they are published in the **Federal Register**. However, BIS finds good cause to waive the 30-day delay in effectiveness for this rule pursuant to 5 U.S.C. 553(d)(3) because the delay would be contrary to the public interest. BIS is simply amending the authorization of an existing VEU by removing an existing eligible destination (facility), revising the address of another eligible destination (facility) to add a building, and removing an eligible item no longer listed on the CCL. BIS amends the EAR in this rule consistent with established objectives and parameters administered and enforced by the responsible designated departmental representatives to the End-User Review Committee. Delaying this action's effectiveness would likely cause confusion regarding which items are authorized by the U.S. Government and in turn stifle the purpose of the VEU Program. Accordingly, it is contrary to the public interest to delay this rule's effectiveness.

No other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required under the APA or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. As a result, no final regulatory flexibility analysis is required and none has been prepared.

List of Subjects in 15 CFR Part 748

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

Accordingly, part 748 of the EAR (15 CFR parts 730–774) is amended as follows:

PART 748—[AMENDED]

■ 1. The authority citation for part 748 continues to read as follows:

Authority: 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2015, 80 FR 48233 (August 11, 2015).

■ 2. Amend Supplement No. 7 to part 748 by revising the entry for "Advanced Micro Devices China, Inc." in "China (People's Republic of)" to read as follows:

SUPPLEMENT NO. 7 TO PART 748—AUTHORIZATION VALIDATED END-USER (VEU): LIST OF VALIDATED END-USERS, RESPECTIVE ITEMS ELIGIBLE FOR EXPORT, RE-EXPORT AND TRANSFER, AND ELIGIBLE DESTINATIONS

Country	Validated end-user	Eligible items (by ECCN)	Eligible destination	**Federal Register** citation
Nothing in this Supplement shall be deemed to supersede other provisions in the EAR, including but not limited to § 748.15(c).				
China (People's Republic of).	Advanced Micro Devices China, Inc.	3D002, 3D003, 3E001 (limited to "technology" for items classified under 3C002 and 3C004 and "technology" for use during the International Technology Roadmap for Semiconductors (ITRS) process for items classified under ECCNs 3B001 and 3B002), 3E002 (limited to "technology" for use during the ITRS process for items classified under ECCNs 3B001 and 3B002), 3E003.e (limited to the "development" and "production" of integrated circuits for commercial applications), 4D001 and 4E001 (limited to the "development" of products under ECCN 4A003).	Advanced Micro Devices (Shanghai) Co., Ltd., Buildings 33 (Unit 1), 46, 47, 48 & 49, River Front Harbor, Zhangjiang Hi-Tech Park, No. 1387 Zhang Dong Road, Pudong District, Shanghai, China 201203. AMD Technology Development (Beijing) Co., Ltd., North and South Buildings, RaycomInfotech, Park Tower C, No. 2 Science Institute South Rd., Zhong Guan Cun, Haidian District, Beijing, China 100190.	75 FR 25763, 5/10/10. 76 FR 2802, 1/18/11. 78 FR 3319, 1/16/13. 81 FR [INSERT PAGE NUMBER], 6/23/16.
Nothing in this Supplement shall be deemed to supersede other provisions in the EAR, including but not limited to § 748.15(c).				
			AMD Products (China) Co. Ltd., North and South Buildings, RaycomInfotech Park Tower C, No. 2 Science Institute South Rd., Zhong Guan Cun, Haidian District, Beijing, China 100190.	

* * * * * * *

Dated: June 17, 2016.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2016–14902 Filed 6–22–16; 8:45 am]

BILLING CODE 3510–33–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 241

[Release No. 34–78102; File No. S7–03–16]

Commission Interpretation Regarding Automated Quotations Under Regulation NMS

AGENCY: Securities and Exchange Commission.

ACTION: Final interpretation.

SUMMARY: The Securities and Exchange Commission is issuing a final interpretation with respect to the definition of automated quotation under Rule 600(b)(3) of Regulation NMS.

DATES: Effective June 23, 2016.

FOR FURTHER INFORMATION CONTACT: Richard Holley III, Assistant Director, Michael Bradley, Special Counsel, or Michael Ogershok, Attorney-Adviser, Office of Market Supervision, at 202–551–5777, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–7010.

SUPPLEMENTARY INFORMATION:

I. Background

Rule 611 of Regulation NMS provides intermarket protection against trade-throughs for "automated" (as opposed to "manual") quotations of NMS stocks. Under Regulation NMS, an "automated" quotation is one that, among other things, can be executed "immediately and automatically" against an incoming immediate-or-cancel order. The Regulation NMS Adopting Release issued in 2005 makes clear that this formulation was intended to distinguish and exclude from protection quotations on manual markets that produced delays measured in seconds in responding to an incoming order, because delays of that magnitude would impair fair and efficient access to an exchange's quotations.[1] In the Regulation NMS Adopting Release, the Commission interpreted the term "immediate" to "preclude[ ] any coding of automated systems or other type of intentional device that would delay the action taken with respect to a quotation."[2]

In light of the application of Investors' Exchange LLC ("IEX")[3] to register as an exchange and technological and market developments since the adoption of Regulation NMS, the Commission decided to revisit this interpretation. The Commission believes its prior interpretation should be updated given technological and market developments since the adoption of Regulation NMS, in particular the emergence of low latency trading strategies and related technology that permit trading decisions to be made in microseconds, neither of which were contemplated by the Commission or commenters in 2005.[4] As further addressed below, the Commission now interprets "immediate" in the context of Regulation NMS as not precluding a *de minimis* intentional delay—*i.e.,* a delay so short as to not frustrate the purposes of Rule 611 by impairing fair and efficient access to an exchange's quotations.[5]

A. Regulation NMS: Automated Quotation and Protected Quotation

In general, Rule 611 under Regulation NMS (the "Order Protection Rule," or "Trade-Through Rule") protects the best "automated" quotations of exchanges by obligating other trading centers to honor those "protected" quotations by not executing trades at inferior prices, or "trading through" such best automated quotations.[6] Only an exchange that is an "automated trading center"[7] displaying an "automated quotation"[8] is entitled to this protection.[9] Trading centers must establish, maintain, and enforce written policies and procedures that are reasonably designed to prevent trade-throughs of protected quotations, unless an exception or exemption applies.[10]

There are several provisions in Regulation NMS that impact whether the Order Protection Rule applies. First, Rule 600(b)(58) defines a "protected quotation" as a "protected bid or a protected offer."[11] Rule 600(b)(57), in turn, defines a "protected bid or protected offer" as a quotation in an NMS stock that is: (i) Displayed by an "automated trading center," (ii) disseminated pursuant to an effective national market system plan, and (iii) an "automated quotation" that is the best bid or best offer of a national securities exchange or national securities association.[12]

In order for an exchange to operate as an "automated trading center," it must, among other things, have "implemented such systems, procedures, and rules as are necessary to render it capable of displaying quotations that meet the requirements for an 'automated quotation' set forth in [Rule 600(b)(3) of Regulation NMS]."[13] Rule 600(b)(3) defines an "automated quotation" as one that:

i. Permits an incoming order to be marked as immediate-or-cancel;

ii. Immediately and automatically executes an order marked as immediate-or-cancel against the displayed quotation up to its full size;

iii. Immediately and automatically cancels any unexecuted portion of an order marked as immediate-or-cancel without routing the order elsewhere;

iv. Immediately and automatically transmits a response to the sender of an order marked as immediate-or-cancel indicating the action taken with respect to such order; and

v. Immediately and automatically displays information that updates the displayed quotation to reflect any change to its material terms.[14]

Any quotation that does not meet the requirements for an automated quotation is defined in Rule 600(b)(37) as a "manual" quotation.[15]

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[1] *See* Securities Exchange Act Release No. 51808 (June 9, 2005) 70 FR 37496, 37500 & n.21, 37501 (June 29, 2005) ("Regulation NMS Adopting Release"). The Commission notes that the smallest time increment suggested by commenters at the time Regulation NMS was adopted was 250 milliseconds. *See id.* at 37518. *See also infra* note 15 (discussing the distinction between "automated quotations" and "manual quotations" and noting that "[t]he difference in speed between automated and manual markets often is the difference between a 1-second response and a 15-second response . . . .").

[2] *See* Regulation NMS Adopting Release, *supra* note 1, at 37534.

[3] *See* Securities Exchange Act Release Nos. 75925 (September 15, 2015), 80 FR 57261 (September 22, 2015) (File No. 10–222) (original notice); and 77406 (March 18, 2016), 81 FR 15765 (March 24, 2016) (File No. 10–222) (notice of amendments, order instituting proceedings, and extension of time).

[4] IEX's Form 1 includes an intentional access delay that imposes 350 microseconds of one-way latency for non-routable orders. IEX's access delay is discussed in the Commission's final order on IEX's Form 1. *See* Securities Exchange Act Release No. 78101 (June 17, 2016) (File No. 10–222) (order granting IEX's exchange registration) ("IEX Form 1 Approval Order").

[5] *See* Regulation NMS Adopting Release, *supra* note 1, at 37520 (noting that "[f]or a trading center to qualify as entitled to display any protected quotations, the public in general must have fair and efficient access to a trading center's quotations").

[6] *See* 17 CFR 242.611. When it adopted Regulation NMS, the Commission explained that one purpose of the Order Protection Rule was to incentivize greater use of displayed limit orders, which contribute to price discovery and market liquidity, by protecting them from trade-throughs. *See* Regulation NMS Adopting Release, *supra* note 1, at 37516–17. In discussing whether to apply order protection to non-automated, "manual" quotations, the Commission stated that "providing protection to manual quotations, even limited to trade-throughs beyond a certain amount, potentially would lead to undue delays in the routing of investor orders, thereby not justifying the benefits of price protection." *Id.* at 37518. The Commission also noted that "those who route limit orders will be able to control whether their orders are protected by evaluating the extent to which various trading centers display automated versus manual quotations." *Id.* In addition, the Commission intended that the Order Protection Rule would reinforce a broker's duty of best execution by prohibiting executions at inferior prices absent an exception. *See id.* at 37516 ("Given the large number of trades that fail to obtain the best displayed prices (*e.g.,* approximately 1 in 40 trades for both Nasdaq and NYSE stocks), the Commission is concerned that many of the investors that ultimately received the inferior price in these trades may not be aware that their orders did not, in fact, obtain the best price. The Order Protection Rule will backstop a broker's duty of best execution on an order-by-order basis by prohibiting the practice of executing orders at inferior prices, absent an applicable exception.").

[7] *See* 17 CFR 242.600(b)(4). References to "exchange" used herein apply also to facilities of national securities associations. *See* 17 CFR 242.600(b)(57).

[8] *See* 17 CFR 242.600(b)(3).

[9] *See* 17 CFR 242.600(b)(57) (defining "protected bid or protected offer") and 242.600(b)(58) (defining "protected quotation"). *See also* Regulation NMS Adopting Release, *supra* note 1, at 37504 (stating that "[t]o qualify for protection, a quotation must be automated").

[10] 17 CFR 242.611(a)(1).

[11] 17 CFR 242.600(b)(58).

[12] 17 CFR 242.600(b)(57).

[13] 17 CFR 242.600(b)(4). Rule 600(b)(4) contains additional requirements that must be satisfied in order to be an automated trading center. Those requirements are not at issue for purposes of this interpretation.

[14] *See* 17 CFR 242.600(b)(3). *See also* Regulation NMS Adopting Release, *supra* note 1, at 37504.

[15] Regulation NMS Adopting Release, *supra* note 1, at 37534. *See also* 17 CFR 242.600(b)(37) (defining "manual quotation"). The Commission also provided context as to the distinction between "automated quotations" and "manual quotations." At the time of the adoption of Regulation NMS, manual quotations and markets that primarily were centered around human interaction in a floor-based trading environment, including "hybrid" manual-automated trading facilities, experienced processing delays for inbound orders that were measured in multiple seconds. *See* Regulation NMS Adopting Release, *supra* note 1, at 37500 n.21 ("One of the primary effects of the Order Protection Rule adopted today will be to promote much greater speed of execution in the market for exchange-listed stocks. The difference in speed between automated and manual markets often is the difference between a 1-second response and a 15-second response . . . ."). In contrast to floor-based and hybrid markets that existed at the time Regulation NMS was adopted, newer automated matching systems coming more widely into use removed the human element and instead immediately matched buyers and sellers electronically. The Commission also explained that the Order Protection Rule took a substantially different approach to intermarket price protection than the existing trade-through protection regime at the time—the Intermarket Trading System ("ITS") Plan. *See id.* at 37501. As the Commission noted, the ITS provisions did not

In adopting Regulation NMS, the Commission recognized that there would be unintentional time delays by automated trading centers in responding to orders, albeit very short ones.[16] Although a number of commenters on Regulation NMS advocated for a specific time standard, ranging from one second down to 250 milliseconds,[17] to distinguish between manual and automated quotations,[18] the Commission declined to set such a standard.[19] Instead, in interpreting the term "immediate[ ]" when adopting Rules 600 and 611, the Commission stated that "[t]he term 'immediate' precludes any coding of automated systems or other type of intentional device that would delay the action taken with respect to a quotation."[20]

The only precise time standards approved by the Commission in Rule 611 and the Regulation NMS Adopting Release arise in the context of two exceptions to Rule 611 covering circumstances in which trade-through protection would not apply. These exceptions illustrate the time dimensions the Commission had in mind in distinguishing quotations that should receive trade-through protection from those that should not, and notably, both use a one-second standard.[21] Specifically, Rule 611(b)(1) provides that trading centers may trade through quotations of automated trading centers that experience a "failure, material delay, or malfunction."[22] The Commission accepted that the "immediate" standard necessarily would accommodate unintentional delays below the threshold of a "material delay," which it interpreted in light of "current industry conditions" as one where a market was "repeatedly failing to respond within one second after receipt of an order."[23] The Commission similarly established a one-second standard for the exception in Rule 611(b)(8), which excepts trade-through protection where the trading center that was traded-through had displayed, within the prior one second, a price equal or inferior to the price of the trade-through transaction.[24] In discussing the 611(b)(8) exception, the Commission stated that it "generally does not believe that the benefits would justify the costs imposed on trading centers of attempting to implement an intermarket price priority rule at the level of sub-second time increments. Accordingly, Rule 611 has been formulated to relieve trading centers of this burden."[25] In adopting these exceptions to Rule 611, the Commission contemplated the existence of very short unintentional delays of a magnitude up to one second that would not affect the protected status of an "immediate" automated quotation. Since then, the market and the technology have evolved.

B. The Commission's Updated Interpretation of Automated Quotation

The Commission proposed to interpret "immediate" when determining whether a trading center maintains an "automated quotation" for purposes of Rule 611 "to include response time delays at trading centers that are *de minimis,* whether intentional or not."[26] The Commission further stated its preliminary belief "that, in the current market, delays of less than a millisecond in quotation response times may be at a *de minimis* level that would not impair a market participant's ability to access a quote, consistent with the goals of Rule 611 and because such delays are within the geographic and technological latencies experienced by market participants today."[27] As discussed below, the Commission received a number of comments on its proposed interpretation and, after considering those comments, has determined to issue a revised interpretation from that which it originally proposed, as detailed further below.

II. Comments Received and Commission Discussion

The Commission received 24 comments[28] on its proposed

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distinguish between manual and automated quotations and "fail[ed] to reflect the disparate speed of response between manual and automated quotations" as they "were drafted for a world of floor-based markets." *Id.* As a result, "[b]y requiring order routers to wait for a response from a manual market, the ITS trade-through provisions can cause an order to miss both the best price of a manual quotation and slightly inferior prices at automated markets that would have been immediately accessible." *Id.* In addition, the Commission emphasized that Rule 611 does not "supplant or diminish" a broker-dealer's duty of best execution. *See id.* at 37538.

[16] *See infra* note 23 and accompanying text (discussing the exception in Rule 611(b)(1) for small unintentional delays).

[17] A millisecond is one thousandth of a second.

[18] *See* Regulation NMS Adopting Release, *supra* note 1, at 37519.

[19] *See id.* at 37519 ("The definition of automated quotation as adopted does not set forth a specific time standard for responding to an incoming order.").

[20] *Id.* at 37534. The Commission also stated that the standard for responding to an incoming order "should be 'immediate,' *i.e.,* a trading center's systems should provide the fastest response possible without any programmed delay." *Id.* at 37519. Further, the Commission also stated that, for a quotation "[t]o qualify as 'automatic,' no human discretion in determining any action taken with respect to an order may be exercised after the time an order is received," and "a quotation will not qualify as 'automated' if any human intervention after the time an order is received is allowed to determine the action taken with respect to the quotation." *Id.* at 37519 and 37534.

[21] *See* 17 CFR 242.611(b)(1) and (8); *see also* Regulation NMS Adopting Release, *supra* note 1, at 37519 (discussing the one-second standard in Rule 611(b)(1)) and *id.* at 37523 (discussing the one-second standard in Rule 611(b)(8)). One second is 1,000,000 microseconds.

[22] 17 CFR 242.611(b)(1).

[23] *See* Regulation NMS Adopting Release, *supra* note 1, at 37519. In other words, the Commission viewed the phrase "fastest response possible" as consistent with an unintentional delay of less than one second whereby participants could consider an automated trading center experiencing a delay beyond that limit to no longer be "immediately" accessible.

[24] *See* 17 CFR 242.611(b)(8).

[25] Regulation NMS Adopting Release, *supra* note 1, at 37523.

[26] Securities Exchange Act Release No. 77407 (March 18, 2016), 81 FR 15660, 15661 (March 24, 2016) (S7–03–16) ("Notice of Proposed Interpretation"). Because IEX's POP/coil delay is designed purposefully and intentionally to delay access to its matching engine, and consequently delays access to IEX's displayed quotation (*See* Letter from Sophia Lee, IEX, to Brent J. Fields, Secretary, Commission, dated November 13, 2015 ("IEX First Form 1 Letter") at 4 (comment letter on File No. 10–222)), IEX would not be an automated market under the interpretation of "immediate" in the Regulation NMS Adopting Release as "[t]he term 'immediate' precludes any coding of automated systems or other type of intentional device that would delay the action taken with respect a quotation." Regulation NMS Adopting Release, *supra* note 1, at 37534.

[27] Notice of Proposed Interpretation, *supra* note 26, at 15665.

[28] *See* Letters ("Interp Letter(s)") from Rajiv Sethi to Brent J. Fields, Secretary, Commission, dated March 21, 2016; Stacius Sakato to Brent J. Fields, Secretary, Commission, dated March 28, 2016; David Lauer, Healthy Markets Association, to Brent J. Fields, Secretary, Commission, dated April 1, 2016; Hazel Henderson, Ethical Markets Media, to Brent J. Fields, Secretary, Commission, dated April 1, 2016; R.T. Leuchtkafer to Brent J. Fields, Secretary, Commission, dated April 8, 2016; Sal Arnuk and Joe Saluzzi, Themis Trading, to Brent J. Fields, Secretary, Commission, dated April 12, 2016; R. Glenn Hubbard, John L. Thornton, and Hal S. Scott, Committee on Capital Markets Regulation, to Brent J. Fields, Secretary, Commission, dated April 14, 2016; Mary Ann Burns, FIA Principal Traders Group, to Brent J. Fields, Secretary, Commission, dated April 14, 2016; William J. Stephenson, Franklin Templeton Investments, to Brent J. Fields, Secretary, Commission, dated April 14, 2016; John Nagel, Citadel, to Brent J. Fields, Secretary, Commission, dated April 14, 2016; Eric Budish to Brent J. Fields, Secretary, Commission, dated April 14, 2016; Bryan Thompson, British Columbia Investment Management Corporation, to Brent J. Fields, Secretary, Commission, dated April 14, 2016; Adam Nunes, Hudson River Trading ("HRT"), to Brent J. Fields, Secretary, Commission, dated April 14, 2016; William R. Harts, Modern Markets Initiative, to Brent J. Fields, Secretary, Commission, dated April 14, 2016; Joan C. Conley, Nasdaq, to Brent J. Fields, Secretary, Commission, dated April 14, 2016; D. Keith Ross, PDQ Enterprises, to Brent J. Fields, Secretary, Commission, dated April 15, 2016; David Weisberger, Markit, to Brent J. Fields, Secretary, Commission, dated April 18, 2016; Elizabeth K. King, NYSE, to Brent J. Fields, Secretary, Commission, dated April 18, 2016; Kevin J. Weldon to Brent J. Fields, Secretary, Commission, dated

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interpretation.[29] Commenters raised a number of issues, including whether intentional sub-millisecond delays are in fact *de minimis* or would materially complicate market structure, as well as requests to clarify the scope and details of the interpretation.

A. De minimis for Purposes of Rule 611

Several commenters questioned whether *de minimis* intentional delays were permissible and whether delays of less than a millisecond could be considered *de minimis* in the current market. One commenter asserted that any intentional delay, even a *de minimis* one, "is flatly inconsistent with the plain meaning of 'immediate[ ],' "[30] referring to the dictionary definition of that term as " '[o]ccurring without delay' or 'instant'."[31] Another commenter asserted that "[o]ne millisecond is not *de minimis* in any context except from the perspective of a human trader" and noted that a millisecond "is over 10 times longer than the response time of most exchanges today."[32] The commenter believed that sub-millisecond delays would "impair a market participant's ability to access a quote."[33] Another commenter argued that a millisecond is "excessively long when compared to computer response times."[34] One commenter believed that a sub-millisecond standard "will become obsolete at faster and faster rates" as communications technology evolves.[35]

Other commenters expressed concern that intentional access delays, even *de minimis* ones, could add unnecessary complexity to the markets. In particular, the commenters stressed that such delays could cause orders to be routed to protected quotes that are no longer available. For example, one commenter expressed concern that the proposed interpretation could turn the national market system "into a hall of mirrors where it's impossible to know which prices are real and which are latent reflections."[36] The commenter opined that intentional access delays would "harm market transparency and degrade the value of the NBBO" and "lead directly to lower fill rates" when orders cannot be filled because the exchange with an access delay displays a stale better-priced quote that no longer exists but has yet to communicate that information.[37] Another commenter argued that the interpretation could make market structure "considerably more complex" and lead to "ghost quotes" that could "cloud price discovery and corrode execution quality."[38] The commenter further noted that "an artificial delay in an exchange quote anywhere affects the markets everywhere" and expressed concern that the proposed interpretation could negatively impact otherwise efficient and accessible markets.[39] One commenter expressed concern that intentional delays might "open the floodgates to a new wave of complex order types" with delays ranging from 1 to 1,000 microseconds.[40] Other commenters, however, opined that intentional access delays would not add complexity to the markets and would fit within current latencies experienced by trading centers. For example, one commenter asserted that a 350 microsecond delay is "not much more than the normal latency that all trading platforms impose," and that an exchange could achieve the same delay by "locat[ing] its primary data center 65 or more miles away from the other exchange data centers."[41]

In response to a comment that the dictionary definition of the term "immediate[ ]" precludes *any* delay in accessing quotations, the Commission notes that quotations cannot be accessed

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April 20, 2016; Sophia Lee, IEX, to Brent J. Fields, Secretary, Commission, dated April 25, 2016; Abraham Kohen, AK Financial Engineering Consultants, to Brent J. Fields, Secretary, Commission, dated April 25, 2016; Theodore R. Lazo, SIFMA, to Brent J. Fields, Secretary, Commission, dated May 2, 2016; The Honorable Randy Hultgren to Mary Jo White, Commission, dated May 2, 2016; Amir C. Tayrani, Gibson, Dunn & Crutcher LLP to Brent J. Fields, Secretary, Commission, dated May 19, 2016.

[29] As discussed and summarized in the Commission's notice of its proposed interpretation, the Commission also received comments on the issue addressed by this interpretation in response to the initial notice of IEX's Form 1. *See* Notice of Proposed Interpretation, *supra* note 26, at 15660, 15663–64. Those comments are also discussed in the Commission's order approving IEX's Form 1 application for exchange registration, which the Commission is separately issuing today. *See* IEX Form 1 Approval Order, *supra* note 4.

[30] Gibson Dunn Interp Letter at 3.

[31] Gibson Dunn Interp Letter at 2 (citing to Black's Law Dictionary and Webster's Third New International Dictionary).

[32] HRT Interp Letter at 2. The commenter further noted that one millisecond is "approximately three times the time via fiber between the furthest New Jersey data centers and approximately ⅛th the time to Chicago via fiber from the New Jersey datacenters." *Id.* at 2–3.

[33] HRT Interp Letter at 2. This commenter also cited to the Commission's MIDAS data from the fourth quarter of 2015, which showed that over 13% of displayed orders in large stocks are cancelled within one millisecond and over 9% of displayed orders in large stocks are executed within one millisecond, and concluded that "[g]iven that over 20% of orders are either executed or canceled during the first millisecond they were displayed, it seems likely that a one millisecond delay would have a material impact on a participant's ability to access the quotations." *See id.* The commenter qualified its observation by noting that these figures are relevant "[t]o the extent that a market with similar order cancellation patterns implemented a one millisecond delay." *See id.* The commenter also recommended that an exchange that imposes an intentional delay "allow market participants to bypass the delay when attempting to access 'protected quotations'." *Id.* at 1–2. *See also* Citadel Interp Letter at 4 ("A time interval in which approximately 10% of executions in many of the most widely traded stocks typically occur is manifestly *not de minimis*."); NYSE Interp Letter at 7. The Commission notes that it is not clear whether an exchange with an access delay that does not offer features (like co-location, post-only orders, or maker-taker fees) that typically attract latency-sensitive traders, who may be more likely to cancel their orders within one millisecond of placing them, would experience those cancellation rates. Further, the Commission notes that Rule 611 focuses on inter-market order protection, which applies only when market participants access protected quotations at geographically dispersed trading centers that are already subject to varying processing delays, some of which may be a millisecond or more. A one millisecond intentional access delay is well within the current geographic and technological latencies already experienced by market participants when routing orders between trading centers.

[34] FIA PTG Interp Letter at 3. The commenter further noted that "[f]or comparison, modern exchange matching engines process orders in considerably less than 1/20 of that time, and geographic latencies between the major exchange data centers in New Jersey are generally less than 1/4 of that time." *Id. See also* Nasdaq Interp Letter at 6 (noting that the throughput time of Nasdaq's system is 40 microseconds); Kohen Interp Letter at 1 (noting that the Bombay Stock Exchange processes a transaction in 6 microseconds).

[35] *See* Nasdaq Interp Letter at 3. *See also* HRT Interp Letter at 3 (noting that "a one millisecond time standard . . . is already obsolete"); FIA PTG Interp Letter at 6 ("One millisecond is slow by today's computer standards, and will be even slower (relatively speaking) in the future."). Some commenters criticized the proposed interpretation as lacking empirical support for a sub-millisecond threshold or consideration of alternative delays. *See* Nasdaq Interp Letter at 4; Citadel Interp Letter at 3; Budish Interp Letter at 2. As discussed above, the Commission notes that the interpretation uses a *de minimis* standard, and not a specific time frame demarcating permissible versus impermissible access delays.

[36] FIA PTG Interp Letter at 2.

[37] FIA PTG Interp Letter at 5. The commenter argued that this might result in the appearance of more locked and crossed markets, which may interfere with market stability during periods of high volatility. *See id.*

[38] PDQ Interp Letter at 1.

[39] *Id.* at 2.

[40] Nasdaq Interp Letter at 3–4; Gibson Dunn Interp Letter at 7.

[41] Letter from James J. Angel to Securities and Exchange Commission, dated December 5, 2015, at 3 (comment letter on IEX Form 1, File No. 10–222). *See also* Letter from Larry Tabb, TABB Group, to Brent J. Fields, Secretary, Commission, dated November 23, 2015, at 1 (comment letter on IEX Form 1, File No. 10–222) (arguing that IEX's 350 microsecond delay is not "particularly problematic, as the time gap is minimal, and (even including the speed bump) IEX matches orders faster than a number of other markets"); Letter from Charles M. Jones to Brent Fields, Secretary, Commission, dated March 2, 2016, at 2 (comment letter on IEX Form 1, File No. 10–222) (noting that "from an economic point of view the 350-microsecond delay [proposed by IEX] per se should not be a particular cause for concern, as it is well within the bounds of the existing, geographically dispersed National Market System, and does not seem likely to contribute substantially to a phantom liquidity problem").

instantaneously.[42] As the Commission repeatedly acknowledged when adopting Regulation NMS, even "immediately" accessible protected quotations in the context of Rules 600 and 611 are necessarily subject to some delay.[43] Specifically, as noted above, the Regulation NMS Adopting Release discussed these delays and, although the Commission declined to set a specific time standard, it contemplated the existence of very short unintentional delays of a magnitude up to one second in the exceptions to Rule 611.

The Commission notes that, when it adopted Regulation NMS in 2005, processing times were longer than they are now.[44] Today, low latency technology permits trading decisions to be made in microseconds, and certain market participants use the fastest gateways and purchase co-location to compete to access quotations at those speeds.[45] As discussed further below, however, even the fastest market participants today must access protected quotations on trading centers where there are delays of several milliseconds as a result of geography alone. In addition, trading centers today are attempting to address concerns with the fastest trading strategies by creating very small delays in accessing their quotations.[46] The Commission does not agree that such efforts are incompatible with the Order Protection Rule. In the context of Regulation NMS, the term "immediate" does not preclude all intentional delays regardless of their duration, and such preclusion is not necessary to achieve the objectives of Rule 611. As long as any intentional delay is *de minimis—i.e.*, does not impair fair and efficient access to an exchange's protected quotations—it is consistent with both the text and purpose of Rule 611.

In response to commenters that argued that an intentional *de minimis* delay would harm market transparency, degrade the NBBO, or cloud price discovery, the Commission notes, as discussed further below, that Rule 600(b)(3)(v) requires trading centers to immediately update their displayed quotations to reflect material changes. Market participants today already necessarily experience very short delays in receiving updates to displayed quotations, as a result of geographic and technological latencies, similar to those experienced when accessing protected quotations. The Commission does not believe the introduction of intentional delays of even smaller magnitude will impair fair and efficient access to protected quotations.

In response to commenters' concern that an intentional delay is not *de minimis* or could add complexity to the market, the Commission notes that its interpretation does not address whether delays are *de minimis* in all trading contexts, but rather only whether they impair fair and efficient access to an exchange's quotations when a market participant routes an order to comply with Rule 611.

Systems processing and transit times, whether at the exchange, the market participant sending the order, or its agent, all create latencies in accessing protected quotations.[47] Even the most technologically advanced market participants today encounter delays in accessing protected quotations of other "away" automated trading centers that either are transitory (*e.g.*, as a result of message queuing) or permanent (*e.g.*, as a result of physical distance). Furthermore, as noted above, any market participant co-located with the major exchanges' data centers in northern New Jersey necessarily encounters delays of 3–4 milliseconds—due to geography alone—in accessing the protected quotations of securities traded on the Chicago Stock Exchange's matching engine in Chicago.[48] No commenter asserted that the periodic message queuing or minor systems-processing delays encountered at exchanges with protected quotations, or the time it takes to access the protected quotes of the Chicago Stock Exchange's Chicago facility, would, for example, materially undermine market quality or price transparency, or the efficiency of order routing or trading strategies.[49]

The Commission acknowledges that interpreting "immediate" to include an intentional *de minimis* access delay, because it would be additive, may increase the overall latency in accessing a particular protected quotation, albeit by a very small amount. Such delays may be a detectable difference for the most latency-sensitive market participants and could marginally impact the efficiency of some of their quoting and trading strategies, even if such intervals likely are immaterial to investors with less advanced trading technology or a longer-term investing horizon. But the Commission believes that just as the geographic and technological delays experienced today do not impair fair and efficient access to an exchange's quotations or otherwise frustrate the objectives of Rule 611, the addition of a *de minimis* intentional access delay is consistent with Rule 600(b)(3)'s "immedia[cy]" requirement.[50]

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[42] *See supra* note 31 (citing to the Gibson Dunn Interp Letter).

[43] For example, the Rule 611(b)(1) exception refers to a "material" delay, which the Commission interpreted as one second or more. *See* Regulation NMS Adopting Release, *supra* note 1, at 37519. In addition, the comment letters on Regulation NMS expressed a multitude of views on the appropriate standard for assessing the accessibility of a protected quotation. *See also supra* text accompanying note 17 (noting that commenters on Regulation NMS who advocated for setting a specific time standard for automated quotations recommended a range of times from one second down to 250 milliseconds).

[44] *See supra* text accompanying note 17 (noting that commenters on Regulation NMS who advocated for setting a specific time standard for automated quotations recommended a range of times from one second down to 250 milliseconds).

[45] Exchanges currently have delays within their systems, including access gateways of varying speeds as well as within their co-location infrastructure. For example, some exchanges intentionally employ a "delay coil" in their co-location facilities or offer different access gateways of varying speeds where one is not as "fast as technologically feasible" as the other. *See* IEX First Form 1 Letter at 3 (comment letter on File No. 10–222) (referring to varying connectivity options offered by exchanges from the NYSE, Nasdaq, and BATS groups, and citing the CEO of Nasdaq referring to the intentional "delay coil" that Nasdaq uses inside its co-location infrastructure). *Compare* Gibson Dunn Interp Letter at 3 (writing on behalf of Nasdaq) (stating "the term 'immediate[]' in Rule 600(b)(3) unambiguously forecloses intentional, planned delay" and referring to "the Commission's own understanding that the term [immediately] requires response times that are as fast as technologically feasible").

[46] *See, e.g., supra* note 45 (discussing intentional delays imposed in the exchange co-location context).

[47] *See supra* note 34 (discussing comments on exchange processing times).

[48] Similarly, they would encounter delays in reaching other "away" exchanges located in other data centers. *See, e.g.*, Letter from David Lauer, Healthy Markets Association, to Brent J. Fields, Secretary, Commission, dated November 6, 2015, at 4 (comment letter on IEX Form 1, File No. 10–222) (noting that "[t]he NBBO already includes quotes with varied degrees of time lag" and that the length of IEX's coiled cable "is far less than the distance between NY and Chicago, and is remarkably similar to the distance between Carteret and Mahwah (36 miles)"); Letter from Sophia Lee, IEX, to Brent J. Fields, Secretary, Commission, dated November 23, 2016, at 4 and 7 (comment letter on IEX Form 1, File No. 10–222) (referring to data from certain subscribers to IEX's ATS that, according to IEX, indicate that those subscribers' average latency when trading on IEX is comparable to that when trading on certain other exchanges, "is an order of magnitude less than that of the Chicago Stock Exchange," and "is on average less than the round-trip latency of the NYSE as well").

[49] From the perspective of a market participant based in New Jersey, classifying a New Jersey market with an intentional sub-millisecond delay as "manual" while classifying a Chicago market with geographic delay measured in multiple milliseconds as "automated" would be inequitable and would not further the goals of Regulation NMS.

[50] One commenter argued that there is "no evidence of a need for a *de minimis* exception or that planned delays will benefit investors in any meaningful way." Gibson Dunn Interp Letter at 7. *See also* Nasdaq Interp Letter at 5. As discussed above, however, the Commission believes that its updated interpretation is warranted in light of

Continued

Further, the Commission notes that its interpretation uses a *de minimis* standard specifically so that it may evolve with technological and market developments. As it did when it established the "immediate" standard, the Commission believes it remains appropriate to avoid "specifying a specific time standard that may become obsolete as systems improve over time." [51] As explained further below, the Commission's revised interpretation provides that the term "immediate" precludes any coding of automated systems or other type of intentional device that would delay the action taken with respect to a quotation unless such delay is *de minimis* in that it would not impair a market participant's ability to fairly and efficiently access a quote, consistent with the goals of Rule 611.

B. Operation of Access Delays

Several commenters that expressed general concerns with an intentional access delay, even a *de minimis* one, expressed a particular concern with those that would be "selectively" applied (*e.g.,* intentional delays that are applied to members but not to the exchange itself).[52] In addition, several commenters asserted that the Commission's proposed interpretation was overbroad based on their belief that it would "permit all sub-millisecond delays, regardless of how those delays operate, the reasoning and incentives behind the delays, or the impacts on the markets and investors." [53] These commenters instead urged the Commission to "evaluate each proposed delay, regardless of its duration, and specifically determine that it is designed and applied in a manner that is consistent with the purposes of the Exchange Act." [54] Another commenter urged the Commission to "take into account not just the length of the delay, but also its *purpose.*" [55]

The Commission notes that this interpretation does not address whether any particular access delay is unfairly discriminatory, an inappropriate or unnecessary burden on competition, or otherwise inconsistent with the Act. Rather, it clarifies that if an intentional access delay is *de minimis,* then it is "immediate" for purposes of Rules 600(b)(3) and 611. While the Commission's interpretation is narrowly focused on the meaning and application of the word "immediate[ ]" in Rule 600(b)(3) in light of technological and market developments since the adoption of Regulation NMS in 2005, the evaluation of any proposed access delay would involve additional considerations.

Specifically, this interpretation does not obviate the requirement of individualized review of proposed access delays, including *de minimis* delays, for consistency with the Exchange Act and Regulation NMS. Any exchange seeking to impose an access delay must reflect that in its rules, which are required to be filed with the Commission as part of the exchange application or as an individual proposed rule change. This interpretation does not alter the requirement that any exchange access delay must be fully described in a written rule of the exchange, which in turn must be filed with the Commission and published for notice and comment, nor does it obviate the need for a proposed rule change that would impose an access delay otherwise to comply with the Act and the regulations thereunder applicable to the exchange.[56] Accordingly, the commenters' concerns and recommended conditions are addressed by the existing requirements and process through which exchanges publicly propose their rule changes under the Act, and each proposed access delay would be scrutinized on an individual basis through that process.[57] Any proposed application of an access delay would therefore be subject to notice, comment, and the Commission's separate evaluation of the proposed rule change.[58]

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technological and market developments and is consistent with the purposes of Rule 611. *See also* comments submitted on IEX's exchange registration (File No. 10–222), a number of which supported the intentional delay proposed by IEX.

[51] Regulation NMS Adopting Release, *supra* note 1, at 37519.

[52] *See, e.g.,* FIA PTG Interp Letter at 6; MMI Interp Letter at 1; Weldon Interp Letter at 1–2.; NYSE Interp Letter at 4; Citadel Interp Letter at 8; Markit Interp Letter at 2–3.

[53] Healthy Markets Interp Letter at 2. *See also* Ethical Markets Interp Letter at 2–3, Franklin Templeton Interp Letter, British Columbia Investment Management Corporation Interp Letter (each repeating the recommendation of the Healthy Markets Interp Letter); and Themis Interp Letter at 2.

[54] Healthy Markets Interp Letter at 3. *See also* Ethical Markets Interp Letter at 2–3, Franklin Templeton Interp Letter, and British Columbia Investment Management Corporation Interp Letter (each repeating the recommendation of the Healthy Markets Interp Letter). The commenters further urged that the interpretation be conditioned on: (1) Delays always being less than one millisecond; (2) delays being applied equally to all participants and across all order types; (3) data sent to the Securities Information Processors should not be delayed; and (4) the purpose of each delay is expressly stated and intended to benefit long-term investors. *See* Healthy Markets Interp Letter at 4. *See also* Ethical Markets Interp Letter at 2–3, Franklin Templeton Interp Letter, and British Columbia Investment Management Corporation Interp Letter (each repeating the recommendation of the Healthy Markets Interp Letter). Another commenter raised a similar concern, and urged the Commission to review each proposed access delay separately and "ensure that any such delays are equally applied to all market participants." *See* Committee on Capital Markets Regulation Interp Letter at 2. One commenter urged the Commission to consider "one single measuring stick: Will the proposed delay serve long term investors?" Themis Interp Letter at 2.

[55] Sethi Interp Letter at 2 (emphasis in original). Another commenter suggested an alternative definition of "immediate" that is not "elapsed-time dependent" but instead would consider an exchange's response to an incoming order to be "immediate" if the transition of the displayed quote from point A (before the order is received) to B (after the order is received) can be "fully attributed to the execution of [the order] in a determinative way." Sakato Interp Letter at 1–2. The Commission believes that at this time an order-by-order determination of whether a quotation is "protected" could introduce unworkable complexity into order routing and could frustrate the incentive provided to market participants to post the resting displayed limit orders that underpin much of the price discovery in the market.

[56] Only registered exchanges and associations can have "automated quotations" that are "protected quotations." *See* 17 CFR 242.611(b)(57). Such entities are required by Section 19 of the Act to file all rules and proposed changes to their rules with the Commission so that the Commission can review and publish them for public notice and comment. *See* 15 U.S.C. 78s(b). Further, no proposed rule change can take effect unless approved by the Commission or otherwise permitted to become effective under the Act and rules thereunder. *See id.* Similarly, an applicant seeking to register as an exchange is required to file all proposed rules with the Commission on Form 1, which the Commission publishes for notice and comment. Once filed, the Commission evaluates each proposed rule change for consistency with the Act and the rules thereunder. An access delay would constitute a "rule" of an exchange because it would be a "stated policy, practice, or interpretation" that concerns a "material aspect" of the operation of an exchange, and thus any new or amended delay would require a filing. *See* 15 U.S.C. 78c(a)(27) (defining "rules of an exchange"); 17 CFR 240.19b–4(a)(6) (defining "stated policy, practice, or interpretation"); 17 CFR 240.19b–4 (noting that a stated policy, practice, or interpretation is deemed to be a proposed change unless it is fairly and reasonably implied by an existing rule or is concerned solely with the administration of the exchange). As required by Section 19(b) of the Act, Rule 19b–4, and Form 19b–4, such exchange would be required to, among other things, detail the purpose of the proposed delay and analyze how the delay is consistent with the Act, including the Section 6 standards governing, among other things, unfair discrimination, protection of investors and the public interest, inappropriate burdens on competition, and just and equitable principles of trade. *See* Section 19(b), Rule 19b–4 and Form 19b–4 (on which exchanges file their proposed rule changes).

[57] *See* Citadel Interp Letter at 6–7 (acknowledging that new access delays would need to be filed with the Commission before they can be implemented, but expressing concern that it would "be exceedingly difficult for the staff to recognize all of the implications and impacts of each delay mechanism").

[58] In the case of IEX, the Commission's separate order approving IEX's Form 1 addresses the POP/coil delay's consistency with the Act. *See also* SIFMA Interp Letter at 3 (recommending that "any intentional delay should be predictable and universally applied to all market participants in a non-discriminatory manner").

C. Other Comments

A few commenters asked the Commission to provide more detail on the application of the proposed interpretation.[59] For example, one commenter asked whether it applies to both inbound and outbound delays and whether it should be based on the exchange's fastest or slowest means of connecting.[60] Other commenters asked how much variance will be permitted and whether unintentional delays also should be covered by the interpretation.[61]

The interpretation of "immediate" applies to the term as used in Rule 600(b)(3), so that it applies to any intentional delay imposed by an exchange through any means provided by the exchange to access its quotations. Further, as modified here from the proposed interpretation, the interpretation applies only to intentional delays, as unintentional delays are addressed by the existing exception contained in Rule 611(b)(1).[62] Finally, in response to the commenters asking if both inbound and outbound delays should be taken into account when measuring the length of an intentional delay, the Commission notes that the intentional delay, as it pertains to the Order Protection Rule, is measured as a cumulative delay experienced by a non-routable order—in other words, the intentional delay applied on an order message sent into an exchange system through each of the events specified in the definition of "automated quotation" in Rule 600(b)(3). Specifically, any intentional delay imposed by the exchange in (1) executing an immediate-or-cancel order against its displayed quotation up to its full size, (2) cancelling any unexecuted portion of such order, or (3) transmitting a response to the sender of such order, should be added together in assessing compliance with Rule 611.[63]

One commenter recommended that the Commission engage in notice and comment rulemaking to effect "a change of this magnitude," which it argued contradicts the "plain meaning of the term 'immediate.' "[64] The commenter argued that an interpretation is only appropriate to "provide guidance on how a new service or product not contemplated at the time a rule was adopted should be treated under existing rules."[65] As discussed above, however, the Commission does not believe the dictionary definition of the term "immediate[ ]" forecloses *de minimis* intentional delays (*i.e.,* intentional delays so short that they do not impair fair and efficient access to an exchange's quotations). The Commission is updating its prior interpretation in light of technological and market developments since the adoption of Regulation NMS in 2005 to accommodate very short intentional delays that do not impair fair and efficient access to protected quotations. Although the Commission did afford an opportunity for notice and comment by publishing a draft interpretation for comment, and did take the comments it received into consideration, the Commission was not required to undertake notice and comment rulemaking when updating its interpretation of its own regulation.

Other commenters focused on what they viewed as a potential opportunity for manipulative activity that could result from an access delay to a market displaying a protected quotation. One commenter opined that an access delay would make it easier to manipulate markets "by taking advantage of stale and inaccessible quotations displayed during the duration of any access delays," and that such manipulative behavior "could be particularly powerful in relatively illiquid stocks."[66] As an example, the commenter posited that a market participant could "safely manipulate a closing auction by sending displayed orders to an exchange with an intentional 999 microsecond delay and timing the submission of those orders for display 998 microseconds or less before the close" because "no other market participant could reach them in time."[67] Another commenter argued that access delays could lead to "stale prices [that] are guaranteed to be displayed for a specific period of time up to 1 millisecond," which would cause pegged orders on other exchanges to "be traded against at known stale prices" when such pegged order is pegged to the stale price on the exchange with the access delay.[68] The commenter argued that this could lead to "a potentially new mechanism for spoofing . . . with the objective of affecting pegged orders on other exchanges."[69]

The Commission notes that the scenarios discussed by commenters are not related to the issue addressed by this interpretation—whether an intentional delay that is so short as not to frustrate the goals of Rule 611 by interfering with fair and efficient access to an exchange's quotations is consistent with Rule 600(b)(3)'s "immedia[cy]" requirement.[70] If a delay is *de minimis*, then whether it is unintentional or intentional in nature is not expected to alter the potential for manipulative activity or make it harder to detect and prosecute. One commenter noted that it is important "to contemplate and address the potential for abuse" [71] when an access delay is proposed and approved. The Commission agrees that such scrutiny—both by the exchange proposing an access delay, and by the Commission when considering whether to approve a proposed access delay rule—would be important. The Commission notes that, pursuant to Section 19(b) and Rule 19b–4, the proposing exchange would be required to consider and address in its rule change filing the potential for abuse of any proposed access delay, which would then be subject to notice, comment, and Commission review. Further, even after the rule change became effective, the Commission believes it would be incumbent on the exchange to remain vigilant in surveilling for abuses and violative conduct of its access delay rule, and consider amending its access delay if necessary, among other considerations, for the protection of investors and the public interest.[72]

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[59] *See, e.g.,* HRT Interp Letter at 3; Nasdaq Interp Letter at 3.

[60] *See* HRT Interp Letter at 3. *See also* Citadel Interp Letter at 9.

[61] *See, e.g.,* Citadel Interp Letter at 9–10. One commenter asked whether there would be a process to remove protected quotation status from an exchange that has an intentional delay that equals or exceeds one millisecond. *See id.* at 10. If any market participant experiences issues in accessing that exchange's quotation, it may consider the applicability of the exceptions specified in Rule 611(b), including the "material delay" condition of Rule 611(b)(1). *See* 17 CFR 242.611(b)(1). The Commission notes that the Rule 611(b)(1) "self-help" exception refers to a "material delay," and in the Regulation NMS Adopting Release, the Commission provided an interpretation of the phrase "material delay" as one where a market was "repeatedly failing to respond within one second after receipt of an order." *See* Regulation NMS Adopting Release, *supra* note 1, at 37519.

[62] *See* 17 CFR 242.611(b)(1). *See also supra* note 61 (discussing the self-help exception). Accordingly, the Commission is not including as part of the interpretation the phrase "whether intentional or not" to focus its interpretation on access delays that are intentional. While the Commission acknowledges that the one-second (*i.e.,* 1,000,000 microseconds) interpretation included in the Regulation NMS Adopting Release for this exception, as well as the "one second" exception in Rule 600(b)(8), may warrant reconsideration in the future, that would be a separate analysis and the Commission is not addressing those exceptions in this interpretation. *See also* SIFMA Interp Letter at 4 (requesting that the Commission clarify that it is not changing the self-help threshold).

[63] *See* 17 CFR 242.600(b)(3)(ii), (iii), and (iv), respectively. *See also* Regulation NMS Adopting Release, *supra* note 1, at 37534. In the case of IEX, the POP/coil delay imposes a 350 microsecond delay inbound to the matching engine for non-routable orders (but no additional delay when cancelling the unexecuted portion of the order) and a 350 microsecond delay outbound on the confirmation back to the order sender, for a cumulative 700 microsecond delay. In addition, the Commission notes that IEX permits incoming orders to be marked as immediate-or-cancel, as is required by Rule 600(b)(3). *See* 17 CFR 242.600(b)(3)(i). One commenter argued that a delay in outbound data could cause the data reported to "not accurately reflect the state of a quotation." *See* Gibson Dunn Interp Letter at 7. This commenter also asserted that intentional delays in communicating reports of transactions would decrease their "informational value." *See* Gibson Dunn Interp Letter at 7; Nasdaq Interp Letter at 2. The Commission notes that the geographic and technological latencies that market participants experience when routing to access a quotation also affect data disseminated from the trading center to the market participant. In other words, market participants already experience latencies when receiving quotation updates and transaction information. At least with respect to delays well within those existing latencies, the Commission does not believe that a market participant's general experience in receiving this information is likely to be altered depending on whether the delay is intentional or unintentional.

[64] Citadel Interp Letter at 1. *See also* Hultgren Interp Letter at 1; Gibson Dunn Interp Letter at 1–2.

[65] Citadel Interp Letter at 2–3.

[66] *Id.* at 6.

[67] *Id.*

[68] NYSE Interp Letter at 8. *See also* Citadel Interp Letter at 8 (arguing that "every time market prices tick up or down, the NBBO would be incorrect for at least the duration of any intentional delays" which would lead some pegged orders to track at "inaccurate prices").

[69] NYSE Interp Letter at 8. *See also* HRT Interp Letter at 3 (citing to a comment from Instinet on IEX's Form 1 that discussed the potential for "spoofing" by entering an order, waiting for 700 microseconds, and cancelling the order without the risk of another market participant seeing or responding to it, but which could provide a false or misleading appearance that could affect the trading of other participants); FIA PTG Interp Letter at 7 (also citing to the Instinet letter).

III. Commission's Interpretation

In response to technological and market developments since the adoption of Regulation NMS,[73] the Commission believes that it is appropriate to provide an updated interpretation of the meaning of the term "immediate" in Rule 600(b)(3).

Solely in the context of determining whether a trading center maintains an "automated quotation" for purposes of Rule 611 of Regulation NMS, the Commission does not interpret the term "immediate" used in Rule 600(b)(3) by itself to prohibit a trading center from implementing an intentional access delay that is *de minimis—i.e.*, a delay so short as to not frustrate the purposes of Rule 611 by impairing fair and efficient access to an exchange's quotations. Accordingly, the Commission's revised interpretation provides that the term "immediate" precludes any coding of automated systems or other type of intentional device that would delay the action taken with respect to a quotation unless such delay is *de minimis*.

The Commission's updated interpretation recognizes that a *de minimis* access delay, even if it involves an "intentional device" that delays access to an exchange's quotation, is compatible with the exchange having an "automated quotation" under Rule 600(b)(3) and thus a "protected quotation" under Rule 611.[74] Under this interpretation, Rule 600(b)(3)'s "immedia[cy]" requirement does not necessarily foreclose an automated trading center's use of very small intentional delays to address concerns arising from low latency trading strategies and other market structure issues. For example, intentional access delays that are well within the geographic and technological latencies experienced by market participants when routing orders are *de minimis* to the extent they would not impair a market participant's ability to access a displayed quotation consistent with the goals of Rule 611.

The interpretation does not change the existing requirement that, prior to being implemented, an intentional delay of any duration must be fully disclosed and codified in a written rule of the exchange that has become effective pursuant to Section 19 of the Act, where the exchange met its burden of articulating how the purpose, operation, and application of the delay is consistent with the Act and the rules and regulations thereunder applicable to the exchange.[75]

In the Notice of Proposed Interpretation, the Commission stated its preliminary belief "that, in the current market, delays of less than a millisecond in quotation response times may be at a *de minimis* level that would not impair a market participant's ability to access a quote, consistent with the goals of Rule 611 and because such delays are within the geographic and technological latencies experienced by market participants today." [76] As discussed above, the Commission received a number of comments on that specific guidance.

At this time, the Commission is not adopting the proposed guidance under this interpretation that delays of less than one millisecond are *de minimis*. The Commission believes that, in light of the evolving nature of technology and the markets, and the need to assess the impact of intentional access delays on the markets, establishing a bright line *de minimis* threshold is not appropriate at this time. Rather, the Commission believes that the interpretation is best focused on whether an intentional delay is so short as to not frustrate the purposes of Rule 611 by impairing fair and efficient access to an exchange's quotations. As it makes findings as to whether particular access delays are *de minimis* in the context of individual exchange proposals,[77] the Commission recognizes that such findings create common standards that must be applied fairly and consistently to all market participants.

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[70] Nevertheless, the Commission believes that the scenarios discussed by commenters would, as a practical matter, be difficult to implement. For example, in the closing auction scenario, the Commission believes it would be practically difficult to successfully implement a coordinated single-digit microsecond strategy during a broad-based auction because of the precision it would require to ensure order arrival at the final microsecond and not have it trade with a multitude of other interest in the auction. Further, concerns surrounding pegged orders on away markets would affect only the most latency sensitive traders and only apply when the exchange with the access delay is alone at the NBBO, has exhausted all displayed and non-displayed interest at its best price, and is in the process of transitioning to a new price. However, that possibility is not uniquely introduced by an exchange with an access delay, but is currently present in a fragmented market with geographically dispersed venues. For example, the same problem (only exacerbated with considerably more latency) would be present if the Chicago Stock Exchange was alone at the NBBO on a symbol it trades from Chicago.

[71] HRT Interp Letter at 3.

[72] *See* 15 U.S.C. 78s(g)(1).

[73] A number of factors affect the speed at which a market participant can receive market and quote data, submit orders, obtain an execution, and receive information on trades, including hardware, software, and physical distance. *See, e.g.*, Securities Exchange Act Release No. 61358 (January 14, 2010), 75 FR 3594, 3610–11 (January 21, 2010) (Concept Release on Equity Market Structure). Recent technological advances have reduced the "latency" that these factors introduce into the order handling process, both in absolute and relative terms, and some market participants and liquidity providers have invested in low-latency systems that take into account the advances in technology. *See id.* at 3606; *see also* Securities Exchange Act Release No. 76474 (November 18, 2015), 80 FR 80997, 81000 (December 28, 2015) (Regulation of NMS Stock Alternative Trading Systems; Proposed Rule) (stating that "[t]he growth in trading centers and trading activity has been fueled primarily by advances in technology for generating, routing, and executing orders" and that "[t]hese technologies have markedly improved the speed, capacity, and sophistication of the trading mechanisms and processes that are available to market participants").

[74] An exchange that proposed to provide any member or user (including the exchange's inbound or outbound routing functionality, or the exchange's affiliates) with *exclusive* privileged faster access to its facilities over any other member or user would raise concerns under the Act, including under Section 6(b)(5) and 6(b)(8) of the Act, and would need to address those concerns in a Form 1 exchange registration application or a proposed rule change submitted pursuant to Section 19 of the Act, as applicable.

[75] As discussed above, any exchange that seeks to impose an intentional access delay must first file a proposed rule change with the Commission, which the Commission would publish for notice and comment, and approve only after finding that it is consistent with the applicable standards set forth in the Act. For example, a proposed access delay that is only imposed on certain market participants or certain types of orders would be scrutinized to determine whether or not the discriminatory application of that delay is unfair. *See, e.g.*, Securities Exchange Act Release No. 77406, 81 FR 15765 (March 24, 2016) (File No. 10–222) (order instituting proceedings on IEX's Form 1) (discussing the potentially unfairly discriminatory application of an access delay to advantage an affiliated outbound routing broker). If the Commission cannot find that a proposed access delay is consistent with the Act, it would disapprove the proposal, rendering moot the issue of whether a quotation with such a delay is protected. Generally, the Commission would be concerned about access delays that were imposed only on certain market participants or intentional access delays that were relieved based upon payment of certain fees.

[76] Notice of Proposed Interpretation, *supra* note 26, at 15665.

The Staff will also conduct a study within two years regarding the effects of intentional access delays on market quality, including price discovery and report back to the Commission with the results of any recommendations. Based on the results of that study or earlier as it determines, the Commission will reassess whether further action is appropriate.

List of Subjects in 17 CFR Part 241

Securities.

Text of Amendments

For the reasons set out in the preamble, the Commission is amending Title 17, chapter II, of the Code of Federal Regulations as follows:

PART 241—INTERPRETATIVE RELEASES RELATING TO THE SECURITIES EXCHANGE ACT OF 1934 AND GENERAL RULES AND REGULATIONS THEREUNDER

Part 241 is amended by adding Release No. 34–78102 to the list of interpretative releases as follows:

Subject	Release No.	Date	Federal Register vol. and page
* * * *		*	* *
Interpretation Regarding Automated Quotations Under Regulation NMS.	34–78102	June 17, 2016	121 FR [Insert FR Page Number].

By the Commission.

Dated: June 17, 2016.

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2016–14876 Filed 6–22–16; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket No. RM16–1–000; Order No. 827]

Reactive Power Requirements for Non-Synchronous Generation

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is eliminating the exemptions for wind generators from the requirement to provide reactive power by revising the *pro forma* Large Generator Interconnection Agreement (LGIA), Appendix G to the *pro forma* LGIA, and the *pro forma* Small Generator Interconnection Agreement (SGIA). As a result, all newly interconnecting non-synchronous generators will be required to provide reactive power at the high-side of the generator substation as a condition of interconnection as set forth in their LGIA or SGIA as of the effective date of this Final Rule.

DATES: This Final Rule will become effective September 21, 2016.

FOR FURTHER INFORMATION CONTACT: Brian Bak (Technical Information), Office of Energy Policy and Innovation, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–6574, *brian.bak@ferc.gov.*

Gretchen Kershaw (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8213, *gretchen.kershaw@ferc.gov.*

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[77] *See supra* note 56 (discussing the proposed rule change process under the Exchange Act). *See also* IEX Form 1 Approval Order, *supra* note 4.

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Order No. 827

Final Rule

1. The Federal Energy Regulatory Commission (Commission) is eliminating the exemptions for wind generators from the requirement to provide reactive power by revising the *pro forma* Large Generator Interconnection Agreement (LGIA), Appendix G to the *pro forma* LGIA, and the *pro forma* Small Generator Interconnection Agreement (SGIA). Under this Final Rule, newly interconnecting non-synchronous generators that have not yet executed a Facilities Study Agreement as of the effective date of this Final Rule will be required to provide dynamic reactive power within the range of 0.95 leading to 0.95 lagging at the high-side of the generator substation. This Final Rule revises the *pro forma* LGIA and *pro forma* SGIA to establish reactive power requirements for non-synchronous generation. Specifically, the *pro forma* LGIA will include the following (the *pro forma* SGIA will include similar language): [1]

> *Non-Synchronous Generation.* Interconnection Customer shall design the Large Generating Facility to maintain a composite power delivery at continuous rated power output at the high-side of the generator substation at a power factor within the range of 0.95 leading to 0.95 lagging, unless the Transmission Provider has established a different power factor range that applies to all non-synchronous generators in the Control Area on a comparable basis. This power factor range standard shall be dynamic and can be met using, for example, power electronics designed to supply this level of reactive capability (taking into account any limitations due to voltage level, real power output, etc.) or fixed and switched capacitors, or a combination of the two. This requirement shall only apply to newly interconnecting non-synchronous generators that have not yet executed a Facilities Study Agreement as of the effective date of the Final Rule establishing this requirement (Order No. 827).

2. Section 35.28(f)(1) of the Commission's regulations requires every public utility with an open access transmission tariff (OATT) on file to also have on file the *pro forma* LGIA and *pro forma* SGIA "required by Commission rulemaking proceedings promulgating and amending such interconnection procedures and agreements." [2] As a result of this Final Rule, all newly interconnecting non-synchronous generators will be required to provide reactive power as a condition of interconnection pursuant to the *pro forma* LGIA and *pro forma* SGIA. These reactive power requirements will apply to any new non-synchronous generator seeking to interconnect to the transmission system that has not yet executed a Facilities Study Agreement as of the effective date of this Final Rule.

3. The existing *pro forma* LGIA and *pro forma* SGIA both require, as a condition of interconnection, an interconnecting generator to design its Generating Facility [3] "to maintain a composite power delivery at continuous rated power output at the Point of Interconnection at a power factor [4] within the range of 0.95 leading to 0.95 lagging" [5] (the reactive power requirement).

4. As discussed below, however, wind generators have been exempt from the general requirement to provide reactive power absent a study finding that the provision of reactive power is necessary to ensure safety or reliability. The Commission exempted wind generators from the uniform reactive power requirement because, historically, the costs to design and build a wind generator that could provide reactive power were high and could have created an obstacle to the development of wind generation.[6] Due to technological advancements, the cost of providing reactive power no longer presents an obstacle to the development of wind generation.[7] The resulting decline in the cost to wind generators of providing

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[1] See Section IV of this Final Rule, *Compliance and Implementation,* for the specific changes to the *pro forma* LGIA and *pro forma* SGIA.

[2] 18 CFR 35.28(f)(1) (2015).

[3] The *pro forma* LGIA defines "Generating Facility" as an "Interconnection Customer's device for the production of electricity identified in the Interconnection Request," excluding the Interconnection Customer's Interconnection Facilities. The *pro forma* LGIA further defines "Large Generating Facility" as a "Generating Facility having a Generating Facility Capacity of more than 20 MW." The *pro forma* SGIA defines "Small Generating Facility" as an "Interconnection Customer's device for the production and/or storage for later injection of electricity identified in the Interconnection Request," excluding the Interconnection Customer's Interconnection Facilities. For purposes of this Final Rule, unless otherwise noted, "Generating Facility" refers to both a Large Generating Facility and a Small Generating Facility.

[4] The power factor of an alternating current transmission system is the ratio of real power to apparent power. Reliable operation of a transmission system requires system operators to maintain a tight control of voltages (at all points) on the transmission system. The ability to vary the ratio of real power to apparent power (*i.e.,* adjust the power factor) allows system operators to maintain scheduled voltages within allowed for tolerances on the transmission system and maintain the reliability of the transmission system. The Commission established a required power factor range in Order No. 2003 of 0.95 leading to 0.95 lagging, but allowed transmission providers to establish different requirements to be applied on a comparable basis. *See Standardization of Generator Interconnection Agreements and Procedures,* Order No. 2003, FERC Stats. & Regs. ¶ 31,146, at P 542 (2003), *order on reh'g,* Order No. 2003–A, FERC Stats. & Regs. ¶ 31,160, *order on reh'g,* Order No. 2003–B, FERC Stats. & Regs. ¶ 31,171 (2004), *order on reh'g,* Order No. 2003–C, FERC Stats. & Regs. ¶ 31,190 (2005), *aff'd sub nom. Nat'l Ass'n of Regulatory Util. Comm'rs* v. *FERC,* 475 F.3d 1277 (D.C. Cir. 2007), *cert. denied,* 552 U.S. 1230 (2008).

[5] Section 9.6.1 of the *pro forma* LGIA and section 1.8.1 of the *pro forma* SGIA.

[6] *Interconnection for Wind Energy,* Order No. 661, FERC Stats. & Regs. ¶ 31,186, at P 51, *order on reh'g,* Order No. 661–A, FERC Stats. & Regs. ¶ 31,198 (2005).

[7] *See, e.g., Payment for Reactive Power,* Commission Staff Report, Docket No. AD14–7, app. 2, at 1–3 (Apr. 22, 2014).

reactive power renders the current absolute exemptions unjust, unreasonable, and unduly discriminatory and preferential. Further, the growing penetration of wind generators on some systems increases the potential for a deficiency in reactive power.[8]

5. Given these changes, the Commission finds under section 206 of the Federal Power Act (FPA)[9] that wind generators should not have an exemption from the reactive power requirement which is unavailable to other generators. While we find that requiring non-synchronous generators to provide dynamic reactive power is now reasonable, we recognize that distinctions between non-synchronous and synchronous generators still exist and that these differences justify requiring non-synchronous generators to provide dynamic reactive power at a different location than synchronous generators: Non-synchronous generators will be required to provide dynamic reactive power at the high-side of the generator substation, as opposed to the Point of Interconnection. The reactive power requirements we adopt here for newly interconnecting non-synchronous generators provide just and reasonable terms, which recognize the technical differences of non-synchronous generators from synchronous generators. These requirements also benefit customers by ensuring that reliability is protected without adding unnecessary obstacles to further development of non-synchronous generators.

I. Background

6. Transmission providers require reactive power to control system voltage for efficient and reliable operation of an alternating current transmission system. At times, transmission providers need generators to either supply or consume reactive power. Starting with Order No. 888,[10] which included provisions regarding reactive power from generators as an ancillary service in Schedule 2 of the *pro forma* OATT, the Commission issued a series of orders intended to ensure that sufficient reactive power is available to maintain the reliability of the bulk power system.

7. Starting with Order No. 2003, the Commission adopted standard procedures and a standard agreement for the interconnection of Large Generating Facilities (the *pro forma* LGIA), which included the reactive power requirement.[11] Under this requirement, large generators must design their Large Generating Facilities to provide 0.95 leading to 0.95 lagging reactive power at the Point of Interconnection. Synchronous generators have met this requirement by providing dynamic reactive power at the Point of Interconnection, utilizing the inherent dynamic reactive power capability of synchronous generators. The Commission recognized in Order No. 2003–A that the *pro forma* LGIA was "designed around the needs of large synchronous generators and that generators relying on newer technologies may find that either a specific requirement is inapplicable or that it calls for a slightly different approach" because such generators "may have unique electrical characteristics."[12] Therefore, the Commission exempted wind generators from this reactive power requirement.[13]

8. In June 2005, the Commission issued Order No. 661,[14] establishing interconnection requirements in Appendix G to the *pro forma* LGIA for large wind generators.[15] Recognizing that, unlike traditional synchronous generators, wind generators had to "install costly equipment" to maintain reactive power capability, the Commission in Order No. 661 preserved the exemption for large wind generators from the reactive power requirement unless the transmission provider shows, through a System Impact Study, that reactive power capability is required to ensure safety or reliability.[16] The Commission explained that this qualified exemption from the reactive power requirement for large wind generators would provide certainty to the industry and "remove unnecessary obstacles to the increased growth of wind generation."[17]

9. In May 2005, the Commission issued Order No. 2006,[18] in which it adopted standard procedures and a standard agreement for the interconnection of Small Generating Facilities (*pro forma* SGIA).[19] In Order No. 2006, the Commission completely exempted small wind generators from the reactive power requirement.[20] The Commission reasoned that, similar to large wind generators, small wind generators would face increased costs to provide reactive power that could create an obstacle to the development of small wind generators. Additionally, the Commission reasoned that small wind generators would "have minimal impact on the Transmission Provider's electric system" and therefore the reliability requirements for large wind generators that were eventually imposed in Order No. 661 were not needed for small wind generators.[21]

10. Since the Commission provided these exemptions from the reactive power requirement for wind generators, the equipment needed for a wind generator to provide reactive power has become more commercially available and less costly, such that the cost of installing equipment that is capable of providing reactive power is comparable

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[8] *See, e.g., PJM Interconnection, L.L.C.*, 151 FERC ¶ 61,097, at P 7 (2015); CAISO Comments at 2–3 (explaining that, in 2014, CAISO had over 11,000 MW of interconnected variable energy resources, the majority of which are non-synchronous generators, but expects to have over 20,000 MW of such resources interconnected by 2024).

[9] 16 U.S.C. 824d–e (2012).

[10] *Promoting Wholesale Competition Through Open Access Non-Discriminatory Transmission Services by Public Utilities; Recovery of Stranded Costs by Public Utilities and Transmitting Utilities*, Order No. 888, FERC Stats. & Regs. ¶ 31,036 (1996), *order on reh'g*, Order No. 888–A, FERC Stats. & Regs. ¶ 31,048, *order on reh'g*, Order No. 888–B, 81 FERC ¶ 61,248 (1997), *order on reh'g*, Order No. 888–C, 82 FERC ¶ 61,046 (1998), *aff'd in relevant part sub nom. Transmission Access Policy Study Group* v. *FERC*, 225 F.3d 667 (D.C. Circuit 2000), *aff'd sub nom. New York* v. *FERC*, 535 U.S. 1 (2002).

[11] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at PP 1, 542.

[12] Order No. 2003–A, FERC Stats. & Regs. ¶ 31,160 at P 407 & n.85.

[13] *Id.* Article 9.6.1 of the *pro forma* LGIA provides: "Interconnection Customer shall design the Large Generating Facility to maintain a composite power delivery at continuous rated power output at the Point of Interconnection at a power factor within the range of 0.95 leading to 0.95 lagging, unless Transmission Provider has established different requirements that apply to all generators in the Control Area on a comparable basis. The requirements of this paragraph shall not apply to wind generators."

[14] *Interconnection for Wind Energy*, Order No. 661, FERC Stats. & Regs. ¶ 31,186, Appendix B (Appendix G—Interconnection Requirements for a Wind Generating Plant), *order on reh'g*, Order No. 661–A, FERC Stats. & Regs. ¶ 31,198 (2005).

[15] *Id.* P 1.

[16] *Id.* PP 50–51. Appendix G states: "A wind generating plant shall maintain a power factor within the range of 0.95 leading to 0.95 lagging, measured at the Point of Interconnection as defined in this LGIA, if the Transmission Provider's System Impact Study shows that such a requirement is necessary to ensure safety or reliability."

[17] *Id.* P 50.

[18] *Standardization of Small Generator Interconnection Agreements and Procedures*, Order No. 2006, FERC Stats. & Regs. ¶ 31,180, Attachment F (Small Generator Interconnection Agreement), *order on reh'g*, Order No. 2006–A, FERC Stats. & Regs. ¶ 31,196 (2005), *order granting clarification*, Order No. 2006–B, FERC Stats. & Regs. ¶ 31,221 (2006).

[19] *Id.* P 1.

[20] *Id.* P 387. Section 1.8.1 of the *pro forma* SGIA states: "The Interconnection Customer shall design its Small Generating Facility to maintain a composite power delivery at continuous rated power output at the Point of Interconnection at a power factor within the range of 0.95 leading to 0.95 lagging, unless the Transmission Provider has established different requirements that apply to all similarly situated generators in the control area on a comparable basis. The requirements of this paragraph shall not apply to wind generators."

[21] *Id.* P 24.

to the costs of a traditional generator.[22] Recognizing these factors, the Commission recently accepted a proposal by PJM Interconnection, L.L.C. (PJM), effectively removing the wind generator exemptions from the PJM tariff.[23] Specifically, the Commission granted PJM an "independent entity variation" from Order No. 661 in accepting PJM's proposal to require interconnection customers seeking to interconnect non-synchronous generators,[24] including wind generators, to use "enhanced inverters" with the capability to provide reactive power.[25] The Commission observed that, "[a]lthough there are still technical differences between non-synchronous generators [such as wind generators] and traditional generators, with regard to the provision of reactive power, those differences have significantly diminished since the Commission issued Order No. 661."[26] The Commission agreed with PJM "that the technology has changed both in availability and in cost since the Commission rejected [the California Independent System Operator's] proposal in 2010," such that "PJM's proposal will not present a barrier to non-synchronous resources."[27]

II. Need for Reform

11. Based upon this information, on November 19, 2015, the Commission issued a Proposal to Revise Standard Generator Interconnection Agreements (NOPR) that proposed to eliminate the exemptions for wind generators from the requirement to provide reactive power as contained in the *pro forma* LGIA, Appendix G to the *pro forma* LGIA, and the *pro forma* SGIA.[28] In the NOPR, the Commission sought comment on: Whether to remove the exemptions for wind generators from the reactive power requirement; whether the current power factor range of 0.95 leading to 0.95 lagging, as set forth in the existing *pro forma* LGIA and *pro forma* SGIA, is reasonable given the technology used by non-synchronous generators; whether newly interconnecting non-synchronous generators should only be required to produce reactive power when the generator's real power output is greater than 10 percent of nameplate capacity; and whether the existing methods used to determine reactive power compensation are appropriate for wind generators and, if not, what alternatives would be appropriate.[29]

12. In response to the NOPR, 24 entities submitted comments,[30] most of which generally support the proposed elimination of the exemptions. However, some commenters seek clarification of various issues that fall into six broad categories: (1) Comments regarding where the reactive power requirement should be measured (the Point of Interconnection, the generator terminals, or elsewhere); (2) comments contesting the proposal to require fully dynamic reactive power capability; (3) comments contesting the proposal to require non-synchronous generators to maintain the required power factor range only when the generator's real power output exceeds 10 percent of its nameplate capacity; (4) comments on compensation methods for reactive power; (5) comments seeking clarification as to which non-synchronous resources the Final Rule will apply; and (6) comments on the need for regional flexibility.

III. Discussion

13. The Commission finds that, given the changes to the cost of providing reactive power by non-synchronous generators, as well as the growing penetration of such generators, the reactive power requirements in the *pro forma* LGIA and *pro forma* SGIA are no longer just and reasonable and are unduly discriminatory and preferential and, thus, need to be revised. We have determined in this Final Rule to apply comparable reactive power requirements to non-synchronous generators and synchronous generators. We recognize technological differences between non-synchronous and synchronous generators still remain. Because of the configuration and means of producing power of synchronous generators, these generators provide dynamic reactive power at the Point of Interconnection. Many commenters point out, however, that the advancements in technology do not permit some non-synchronous generators to provide dynamic reactive power at reasonable cost at the Point of Interconnection. Recognizing the differences between the two categories of generation, we have determined to require non-synchronous generators to provide dynamic reactive power at the high-side of the generator substation.[31]

14. The requirements adopted by this Final Rule are intended to ensure that all generators, both synchronous and non-synchronous, are treated in a not unduly discriminatory or preferential manner, as required by sections 205 and 206 of the FPA, and to ensure sufficient reactive power is available on the bulk power system as more non-synchronous generators seek to interconnect and more synchronous generators retire.

15. We discuss below the issues raised in the comments.

A. Reactive Power Requirement for Non-Synchronous Generators

1. NOPR Proposal

16. In the NOPR, the Commission proposed to eliminate the exemptions for wind generators from the reactive power requirement, and thereby to require that all newly interconnecting non-synchronous generators provide reactive power as a condition of interconnection.[32]

2. Comments

17. Most commenters agree that the current exemptions for wind generators from the reactive power requirement are unjust, unreasonable, and unduly discriminatory and preferential due to increases in the number and size of non-synchronous generators, and advances in non-synchronous generator technology.[33] Commenters contend that operation and planning of the bulk power system requires adequate levels of voltage support, and that exempting wind generators from the reactive power requirement may inhibit the proper

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[22] *See, e.g., Payment for Reactive Power,* Commission Staff Report, Docket No. AD14–7, app. 1, at 6, app. 2, at 4–5 (Apr. 22, 2014).

[23] *PJM Interconnection, L.L.C.,* 151 FERC ¶ 61,097 at P 28.

[24] Non-synchronous generators are "connected to the bulk power system through power electronics, but do not produce power at system frequency (60 Hz)." They "do not operate in the same way as traditional generators and respond differently to network disturbances." *Id.* P 1 n.3 (citing Order No. 661, FERC Stats. & Regs. ¶ 31,198 at P 3 n.4). Wind and solar photovoltaic generators are two examples of non-synchronous generators.

[25] *Id.* PP 1, 6.

[26] *Id.* P 28.

[27] *Id.*

[28] *Reactive Power Requirements for Non-Synchronous Generation,* Notice of Proposed Rulemaking, 80 Fed Reg. 73,683 (Nov. 25, 2015), FERC Stats. & Regs. ¶ 32,712 (2015).

[29] *Id.* P 18.

[30] *See* Appendix A for a list of entities that submitted comments and the shortened names used throughout this Final Rule to describe those entities.

[31] This measurement point is different from Order No. 2003 requirement, which measures the power factor at the Point of Interconnection. As an example, the generator substation would be the substation for a wind generator that separates the low-voltage collector system from the higher voltage elements of the Interconnection Customer Interconnection Facilities that bring the generator's energy to the Point of Interconnection. Both the *pro forma* Large Generator Interconnection Procedures and the *pro forma* Small Generator Interconnection Procedures require interconnecting generators to provide a simplified one-line diagram of the plant and station facilities, which will be appended to the interconnection agreement.

[32] NOPR, FERC Stats. & Regs. ¶ 32,712 at P 12.

[33] EEI Comments at 5; Indicated NYTOs Comments at 2–3; ISO/RTO Council Comments at 4; ISO–NE Comments at 9–10; MISO Comments at 2.

operation of the bulk power system.[34] Specifically, commenters assert that non-synchronous generators are increasingly replacing synchronous generators, which is resulting in a decrease in the amount of dynamic reactive power available to the transmission system.[35] Commenters also contend that the inverters used by most non-synchronous generators today are manufactured with the inherent capability to produce reactive power.[36] Therefore, commenters generally support the Commission's proposal to create comparable reactive power requirements for non-synchronous and synchronous generators.[37] While the Public Interest Organizations support the removal of the exemptions for wind generators from the reactive power requirement, they ask that the Commission not impose unduly burdensome requirements on non-synchronous generators.[38]

18. Commenters argue that it is more effective to have a standard reactive power requirement for wind generators than requiring transmission providers to show through a System Impact Study the need for reactive power from an interconnecting wind generator on a case-by-case basis because a System Impact Study may not reflect the future needs of the transmission system.[39] CAISO explains that deficiencies in reactive power support may only become apparent when there are high levels of variable energy resources and low demand, or when certain transmission infrastructure or synchronous generators are out of service.[40] Because System Impact Studies do not study all conditions, CAISO contends they may not capture these deficiencies before a wind generator interconnects to the transmission system.[41] Therefore, CAISO, as well as the ISO/RTO Council, assert that transmission providers may need to remedy deficiencies in reactive power support that were not identified through a System Impact Study through authorization and development of transmission infrastructure upgrades.[42]

19. Commenters argue that relying on transmission system upgrades after a wind generator interconnects, or relying on more recently interconnected generation resources, to meet reactive power deficiencies may shift the cost of providing reactive power from one interconnection customer to another. Specifically, if a System Impact Study does not show that an earlier interconnecting wind generator needs to provide reactive power, but, as a result of the combination of existing and new wind generators, a System Impact Study for a later interconnecting wind generator does make that showing, the newer interconnecting wind generator would have the entire burden of supplying reactive power instead of sharing equally with the other wind generators creating the need for reactive power.[43] Further, commenters assert that requiring transmission providers to show through a System Impact Study the need for reactive power from interconnecting wind generators leads to delays and increased costs in processing interconnection requests.[44] Commenters argue that a uniform reactive power requirement for non-synchronous generators may result in reduced costs for wind development by allowing standardization of components and equipment.[45] Additionally, ISO–NE argues that the difficulty in demonstrating a need for reactive power through a System Impact Study has resulted in some wind generators not being required to install reactive power equipment and, consequently, not being able to deliver real power during certain system conditions as a result of insufficient reactive power capability.[46] According to ISO–NE., this situation has resulted in transmission system operators needing to curtail wind generators as a result of unstudied real-time system characteristics.[47]

20. Several independent system operators (ISOs) and regional transmission organizations (RTOs) have been developing new reactive power requirements and procedures to address deficiencies in the current method of requiring transmission providers to show through a System Impact Study that reactive power from an interconnecting wind generator is necessary to ensure safety or reliability.[48]

3. Commission Determination

21. Based on the comments filed in response to the NOPR, and the record in the PJM and ISO–NE proceedings accepting PJM's and ISO–NE's reactive power requirements for non-synchronous generators,[49] the Commission adopts in this Final Rule reactive power requirements for newly interconnecting non-synchronous generators, as discussed in greater detail below. We find the continued exemptions from the reactive power requirement in the *pro forma* LGIA and the *pro forma* SGIA for newly interconnecting wind generators to be unjust, unreasonable, and unduly discriminatory and preferential.

22. Non-synchronous generators other than wind generators currently are not exempt from the reactive power requirement in the *pro forma* LGIA and *pro forma* SGIA,[50] although the Commission has treated other types of non-synchronous generators in the same manner as wind generators on a case-by-case basis.[51] We proposed in the NOPR[52] to apply the Final Rule to all *non-synchronous* generators, and received no adverse comments. This Final Rule will apply to all newly

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[34] CAISO Comments at 2–5; ISO/RTO Council Comments at 5; ISO–NE Comments at 9; NERC Comments at 5–6; Six Cities Comments at 3–4.

[35] CAISO Comments at 2–3; EEI Comments at 4–5; ITC Comments at 1–2; SCE Comments at 2; SDG&E Comments at 2.

[36] CAISO Comments at 3; ISO/RTO Council Comments at 5; MISO Comments at 2–3; NaturEner Comments at 2; NERC Comments at 9; SCE Comments at 2.

[37] CAISO Comments at 3; EEI Comments at 6–7; EPSA Comments at 3; Idaho Power Comments at 1; Indicated NYTOs Comments at 2; ISO/RTO Council Comments at 4; ISO–NE Comments at 7–8; ITC Comments at 1; Lincoln Comments at 1–2; MISO Comments at 1–2; NEPOOL Initial Comments at 6; SCE Comments at 2; SDG&E Comments at 3.

[38] Public Interest Organizations Comments at 1.

[39] CAISO Comments at 4–5; EEI Comments at 5–6; ISO/RTO Council Comments at 5; ISO–NE Comments at 2.

[40] CAISO Comments at 4.

[41] *Id.*

[42] CAISO Comments at 4; ISO/RTO Council Comments at 5.

[43] ISO/RTO Council Comments at 5; Union of Concerned Scientists Comments at 4–5.

[44] ISO–NE Comments at 2, 4, 10; NEPOOL Initial Comments at 5.

[45] Indicated NYTOs Comments at 2; Joint NYTOs Comments at 2.

[46] ISO–NE Comments at 5.

[47] *Id.* at 6.

[48] CAISO Comments at 1–2; ISO–NE Comments at 6; NEPOOL Initial Comments at 4.

[49] On April 15, 2016, after issuing the NOPR and receiving comments, the Commission approved ISO–NE's proposal to eliminate the exemptions for wind generators from the reactive power requirement. *ISO New England Inc.*, 155 FERC ¶ 61,031 (2016). The Commission previously accepted PJM's similar proposal. *See PJM Interconnection, L.L.C.*, 151 FERC ¶ 61,097 (2015).

[50] Order Nos. 2003, 661, and 2006 explicitly exempted only wind generators from the reactive power requirement. *See* Order No. 661, FERC Stats. & Regs. ¶ 31,186 at P 106 ("While we are not applying the Final Rule Appendix G to non-wind technologies, we may do this in the future, or take other generic or case-specific actions, if another technology emerges for which a different set of interconnection requirements is necessary.").

[51] *See Nevada Power Co.*, 130 FERC ¶ 61,147, at P 27 (2010) ("[C]onsistent with our requirements for all wind facilities in Order No. 661, the Commission will require based on the facts of this case, that, before Nevada Power may require El Dorado's solar facility to be capable of providing reactive power, Nevada Power must show, through a system impact study, that such a requirement is necessary to ensure the safety or reliability of the grid."); *id.* P 24 ("We agree . . . that this is not the appropriate proceeding in which to make a generic determination on whether to extend to solar generators wind power's exemption from the requirement to provide reactive power support.").

[52] *E.g.*, NOPR, FERC Stats. & Regs. ¶ 32,712 at P 17.

interconnecting non-synchronous generators that have not yet executed a Facilities Study Agreement as of the effective date of this Final Rule.

23. Older wind turbine generators consumed reactive power, but, because they did not use inverters like other non-synchronous generators, they lacked the capability to produce and control reactive power without the use of costly equipment.[53] Based on technological improvements since the Commission created the exemptions for wind generators, requiring newly interconnecting wind generators to provide reactive power is not the obstacle to the development of wind generation that it was when the Commission issued Order Nos. 2003, 661, and 2006.[54] In particular, the wind turbines being installed today are generally Type III and Type IV inverter-based turbines,[55] which are capable of producing and controlling dynamic reactive power, which was not the case in 2005 when the Commission exempted wind generators from the reactive power requirement in Order No. 661.[56]

24. We therefore conclude that improvements in technology, and the corresponding declining costs for newly interconnecting wind generators to provide reactive power, make it unjust, unreasonable, and unduly discriminatory and preferential to exempt such non-synchronous generators from the reactive power requirement when other types of generators are not exempt. Further, requiring all newly interconnecting non-synchronous generators to design their Generating Facilities to maintain the required power factor range ensures they are subject to comparable requirements as other generators.[57]

25. The Commission also is concerned that, as the penetration of non-synchronous generators continues to grow, exempting a class of generators from providing reactive power could create reliability concerns, especially if those generators represent a substantial amount of total generation in a particular region, or if many of the resources that currently provide reactive power are retired from operation. In addition, as noted above, maintaining the exemptions for wind generators places an undue burden on synchronous generators to supply reactive power without a reasonable technological or cost-based distinction between synchronous and non-synchronous generators.[58] Therefore, the Commission concludes that the continued exemptions from the reactive power requirement for newly interconnecting wind generators are unjust, unreasonable, and unduly discriminatory and preferential. For these reasons, the Commission revises the *pro forma* LGIA, Appendix G to the *pro forma* LGIA, and the *pro forma* SGIA to eliminate the exemptions for wind generators from the reactive power requirement.[59]

B. Power Factor Range, Point of Measurement, and Dynamic Reactive Power Capability Requirements

1. NOPR Proposal

26. The Commission proposed in the NOPR as part of the reactive power requirements for non-synchronous generators to require all newly interconnecting non-synchronous generators to design their Generating Facilities to maintain a composite power delivery at continuous rated power output at the Point of Interconnection at a power factor within the range of 0.95 leading to 0.95 lagging.[60] Further, the Commission proposed to require that the reactive power capability installed by non-synchronous generators be dynamic.[61]

2. Comments

27. Several commenters support the Commission's proposal to measure the reactive power requirement at the Point of Interconnection.[62] Commenters note that measuring the reactive power requirement at the Point of Interconnection is consistent with the current requirement in the *pro forma* LGIA for measuring the reactive power requirement where a transmission provider's System Impact Study shows the need for reactive power from an interconnecting wind generator.[63] Midwest Energy argues that transmission providers are only concerned with power factor and voltage at the Point of Interconnection.[64] CAISO asserts that measuring the reactive power requirement at the Point of Interconnection gives interconnection customers flexibility in how they design their generator projects to meet the reactive power requirement.[65] CAISO states that inverter manufacturers informed CAISO that current inverters used by most non-synchronous generators are capable of producing 0.95 leading and 0.95 lagging reactive power at full real power output at the generator's Point of Interconnection.[66] NextEra acknowledges that the common approach within ISOs/RTOs is to measure reactive power at the Point of Interconnection, but suggests that if reactive power is measured at the Point of Interconnection, then the Commission should maintain the flexibility for non-synchronous generators to meet that requirement using static reactive power devices if agreed to by the transmission provider, as provided for in Appendix G to the *pro forma* LGIA.[67] NaturEner asserts that, depending on the length of the collector system, transformer substation characteristics, and the length of the

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[53] Order No. 661, FERC Stats. & Regs. ¶ 31,186 at PP 50–51.

[54] As discussed above, in exempting wind generators from the reactive power requirement, the Commission sought to avoid creating an obstacle to the development of wind generation. For example, in Order No. 661, the Commission was concerned with "remov[ing] unnecessary obstacles to the increased growth of wind generation." *Id.* P 50.

[55] A Type III wind turbine is a non-synchronous wound-rotor generator that has a three phase AC field applied to the rotor from a partially-rated power-electronics converter. A Type IV wind turbine is an AC generator in which the stator windings are connected to the power system through a fully-rated power-electronics converter. Both Type III and Type IV wind turbines have inherent reactive power capabilities.

[56] *Id.* PP 50–51.

[57] *See, e.g., Sw. Power Pool, Inc.*, 119 FERC ¶ 61,199, at P 29 ("Providing reactive power within the [standard power factor range] is an obligation of a generator, and is as much an obligation of a generator as, for example, operating in accordance with Good Utility Practice."), *order on reh'g*, 121 FERC ¶ 61,196 (2007).

[58] *See PJM Interconnection, L.L.C.*, 151 FERC ¶ 61,097 at P 7; *Payment for Reactive Power*, Commission Staff Report, Docket No. AD14–7, app. 1 (Apr. 22, 2014).

[59] The Final Rule does not revise any regulatory text. The Final Rule revises the *pro forma* LGIA and *pro forma* SGIA in accordance with section 35.28(f)(1) of the Commission's regulations, which provides: "Every public utility that is required to have on file a non-discriminatory open access transmission tariff under this section must amend such tariff by adding the standard interconnection procedures and agreement and the standard small generator interconnection procedures and agreement required by Commission rulemaking proceedings promulgating and amending such interconnection procedures and agreements, or such other interconnection procedures and agreements as may be required by Commission rulemaking proceedings promulgating and amending the standard interconnection procedures and agreement and the standard small generator interconnection procedures and agreement." 18 CFR 35.28(f)(1) (2015). *See Integration of Variable Energy Resources*, Order No. 764, FERC Stats. & Regs. ¶ 31,331, at PP 343–345 (adopting this regulatory text effective September 11, 2012), *order on reh'g and clarification*, Order No. 764–A, 141 FERC ¶ 61,232 (2012), *order on clarification and reh'g*, Order No. 764–B, 144 FERC ¶ 61,222 (2013). While not revising regulatory text, the Commission is using the process provided for rulemaking proceedings, as defined in 5 U.S.C. 551(4)–(5) (2012).

[60] NOPR, FERC Stats. & Regs. ¶ 32,712 at P 16.

[61] *Id.* P 14.

[62] CAISO Comments at 6; EEI Comments at 8; Indicated NYTOs Comments at 4; Midwest Energy Comments at 9; NERC Comments at 9.

[63] CAISO Comments at 6; EEI Comments at 7.

[64] Midwest Energy Comments at 9.

[65] CAISO Comments at 6.

[66] *Id.* at 3.

[67] NextEra Comments at 10–11.

Interconnection Customer Interconnection Facilities from the generator terminals to the Point of Interconnection, it may not be possible for non-synchronous generators to meet the 0.95 leading to 0.95 lagging reactive power requirement at the Point of Interconnection without installing additional equipment.[68]

28. On the other hand, some commenters disagree with the NOPR proposal and argue that the reactive power requirement should be measured at the generator terminals rather than at the Point of Interconnection for non-synchronous generators. They assert that measuring at the Point of Interconnection would result in significantly higher costs for non-synchronous generators than measuring at the generator terminals. They also argue that, because of the often significant distance between non-synchronous generator terminals and the Point of Interconnection, measuring the reactive power requirement for non-synchronous generators at the generator terminals would result in a reactive power requirement that is comparable to measuring at the Point of Interconnection for synchronous generators.[69] AWEA and LSA contend that synchronous and non-synchronous generators are not similarly situated due to the fact that non-synchronous generators are typically located geographically and electrically farther from the Point of Interconnection than synchronous generators.[70] Therefore, AWEA and LSA request that non-synchronous generators have the option to meet the reactive power requirement at the generator terminals, even if the requirement at that point is more stringent (*e.g.*, 0.95 leading to 0.90 lagging) than at the Point of Interconnection.[71] AWEA and LSA note that they supported the independent entity variation from Order No. 661 in PJM in part because the reactive power requirement is measured at the generator terminals.[72]

29. Some commenters argue that, due to the configuration of typical non-synchronous generators, additional investment is required to supplement the inherent dynamic reactive power capability of the generators to meet the reactive power requirement at the Point of Interconnection; therefore, they assert that requiring measurement at the Point of Interconnection would reset the costs for non-synchronous generators to a level higher than that which the Commission considered in approving PJM's independent entity variation.[73] In addition to equipment investment, AWEA and LSA contend that, in many situations, providing excess reactive power at the generator terminals to meet the reactive power requirement at the Point of Interconnection would result in a large decrease in real power output, and accompanying lost opportunity costs and lost zero-emission, zero-fuel cost energy.[74] Similarly, NaturEner argues that the proposed power factor range of 0.95 leading to 0.95 lagging is only reasonable if the reactive power requirement is measured at the generator terminals.[75] NaturEner contends that measuring the reactive power requirement at the generator terminals will result in sufficient voltage control at the Point of Interconnection.[76] Alternatively, NaturEner also suggests that it would be reasonable to require a power factor range of 0.95 leading to 0.95 lagging at the generator substation.[77] Finally, NaturEner argues that any additional reactive power needs could be determined in a System Impact Study.[78]

30. While CAISO allows synchronous generators to provide reactive power at the generator terminals, CAISO does not support providing this option to non-synchronous generators. CAISO argues that measuring the reactive power requirement at the generator terminals is inappropriate for non-synchronous generators because non-synchronous generators often use multiple transformers, collection circuits, and substations to transmit real power across lengthy Interconnection Customer Interconnection Facilities from the generator terminal to the Point of Interconnection, reducing the amount of reactive power that reaches the transmission system. In contrast, CAISO explains that the configuration of synchronous generators typically involves a single transformer and short Interconnection Customer Interconnection Facilities from the generator terminal to the Point of Interconnection, making measuring the reactive power requirement at the generator terminals for synchronous generators appropriate for ensuring that sufficient reactive power is provided to the transmission system.[79]

31. As to the Commission's proposal to require fully dynamic reactive power capability, commenters in support argue that requiring dynamic reactive power capability allows generators to operate across a broader range of operating conditions than allowing static reactive power devices.[80] ISO–NE asserts that requiring fully dynamic reactive power capability is consistent with the historic requirement that synchronous generators provide dynamic reactive power.[81] ISO–NE contends that generators are more effective at providing dynamic reactive power compared to transmission infrastructure.[82]

32. Conversely, other commenters disagree with the proposal to require fully dynamic reactive power capability. SDG&E contends that such a requirement is not necessary and that allowing non-synchronous generators to use static reactive power devices to meet the reactive power requirement will provide flexibility to generator developers and keep costs at a reasonable level.[83] SDG&E suggests that the dynamic reactive power capability requirement only be for 0.985 leading to 0.985 lagging reactive power capability.[84] Other commenters assert that the existing *pro forma* LGIA and *pro forma* SGIA neither define "dynamic" reactive power capability, nor specify a mix of static versus dynamic reactive power capability that a generator must maintain, and that the Commission should not specify such a mix in this proceeding.[85] Rather, AWEA and LSA argue that it would be discriminatory to require non-synchronous generators to maintain fully dynamic reactive power capability because their configuration results in significant loss of dynamic reactive power from the generator terminal to the Point of Interconnection. Instead, AWEA and LSA argue that static reactive power devices are necessary and effective to supplement the dynamic reactive power capability of the generator to provide reactive power at the Point of Interconnection.[86]

33. NextEra argues that if the proposed reactive power requirement is

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[68] NaturEner Comments at 3.

[69] AWEA and LSA Comments at 12; Joint NYTOs Comments at 3–4; Public Interest Organizations Comments at 2; Union of Concerned Scientists Comments at 3.

[70] AWEA and LSA Comments at 12.

[71] *Id.* at 10, 12–13.

[72] *Id.* at 10–11.

[73] AWEA and LSA Comments at 10–12; NextEra Comments at 9; Union of Concerned Scientists Comments at 3–4.

[74] AWEA and LSA Comments at 11.

[75] NaturEner Comments at 3.

[76] *Id.* at 3–4.

[77] *Id.* at 3.

[78] *Id.* at 4; *see also* Midwest Energy Comments at 10.

[79] CAISO Comments at 6–7.

[80] EEI Comments at 8; ISO–NE Comments at 8.

[81] ISO–NE Comments at 8.

[82] *Id.* at 9.

[83] SDG&E Comments at 3–4.

[84] *Id.* at 4.

[85] AWEA and LSA Comments at 8; EEI Comments at 8; Midwest Energy Comments at 5; NextEra Comments at 6.

[86] AWEA and LSA Comments at 9; *see also* Midwest Energy Comments at 6.

for fully dynamic reactive power capability, then measuring the requirement at the generator terminals for non-synchronous generators is required to ensure comparable treatment to synchronous generators.[87] NextEra contends that the cost of providing reactive power is manageable at the Point of Interconnection if the flexibility provided in section 9.6.1 of the *pro forma* LGIA is maintained and the reactive power requirement can be met with static reactive power devices, but that the requirement could be cost-prohibitive if non-synchronous generators are required to install dynamic reactive power devices.[88] Commenters request that the Commission clarify that it did not intend to specify that a non-synchronous generator must meet the reactive power requirement with only dynamic reactive power capability.[89] Specifically, NextEra argues that the Commission should not remove paragraph A.ii of Appendix G to the *pro forma* LGIA because it provides important provisions regarding the types of devices that can be used to meet the reactive power requirement.[90]

3. Commission Determination

34. We will require the reactive power requirements in the *pro forma* LGIA and *pro forma* SGIA for non-synchronous generators to be measured at the high-side of the generator substation. Newly interconnecting non-synchronous generators will be required to design their Generating Facilities to maintain a composite power delivery at continuous rated power output at the high-side of the generator substation. At that point, the non-synchronous generator must provide dynamic reactive power within the power factor range of 0.95 leading to 0.95 lagging, unless the transmission provider has established a different power factor range that applies to all non-synchronous generators in the transmission provider's control area on a comparable basis.[91] To ensure there is no undue discrimination, we clarify that the ability of a transmission provider to establish different requirements is limited to establishing a different power factor range, and not to the other reactive power requirements.

35. Non-synchronous generators may meet the dynamic reactive power requirement by utilizing a combination of the inherent dynamic reactive power capability of the inverter, dynamic reactive power devices (*e.g.,* Static VAR Compensators), and static reactive power devices (*e.g.,* capacitors) to make up for losses. In developing this reactive power requirement for non-synchronous generators, the Commission is balancing the costs to newly-interconnecting non-synchronous generators of providing reactive power with the benefits to the transmission system of having another source of reactive power.

36. Although the Commission in the NOPR considered measuring the reactive power requirements for non-synchronous generators at the Point of Interconnection, we are persuaded by commenters' arguments that requiring fully dynamic reactive power capability at the Point of Interconnection may result in significantly increased costs for non-synchronous generators in meeting the reactive power requirements.[92] These added costs will ultimately be borne by customers, whether through reactive power payments in regions that compensate for reactive power capability, or through elevated prices for capacity or energy in regions that do not compensate for reactive power capability. In contrast, measuring the reactive power requirements at the high-side of the generator substation, rather than at the Point of Interconnection, will be less expensive for non-synchronous generators because a greater amount of the inherent dynamic reactive power capability of the inverters associated with non-synchronous generators will be available at the high-side of the generator substation than at the Point of Interconnection.

37. In adopting the Point of Interconnection as the point of measurement for large wind plants in Order No. 661, the Commission balanced the case-by-case reactive power requirement with the needs of the transmission system.[93] Here, we remove the case-by-case approach, and require that all newly interconnecting non-synchronous generators provide reactive power as a condition of interconnection. By requiring *all* newly interconnecting non-synchronous generators to provide reactive power, we are increasing the amount of reactive power available to meet transmission system needs, and, at the same time, balancing the costs to non-synchronous generators of providing that reactive power by measuring the requirements at the high-side of the generator substation.

38. Similarly, in Order No. 661, the Commission was not convinced that dynamic reactive power capability was needed from every wind generator, and so adopted the case-by-case approach.[94] However, with the increasing penetration of wind generation and retirement of traditional synchronous generators, which provided dynamic reactive power capability to the transmission system, we now find it is necessary to require dynamic reactive power capability from all new generators. The dynamic reactive power capability may be achieved at the high-side of the generator substation at lower cost compared to dynamic reactive power at the Point of Interconnection by systems using a combination of dynamic capability from the inverters plus static reactive power devices to make up for losses. Therefore, this Final Rule gives non-synchronous generators the flexibility to use static reactive power devices to make up for losses that occur between the inverters and the high-side of the generator substation, so long as the generators maintain 0.95 leading to 0.95 lagging dynamic reactive power capability at the high-side of the generator substation.

39. While measuring the reactive power requirements at the Point of Interconnection would provide the greatest amount of reactive power to the transmission system, the costs associated with providing that level of reactive power do not justify the added benefit to the transmission system.[95] In

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[87] NextEra Comments at 9–10.

[88] *Id.* at 9; NextEra Supplemental Comments at 4.

[89] AWEA and LSA Comments at 9; Midwest Energy Comments at 6; NextEra Comments at 7.

[90] NextEra Comments at 8.

[91] Under these provisions, transmission providers may establish a different power factor range for synchronous or non-synchronous generators as long as the requirement applies to all generators in each class on a comparable basis. *See* Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 542 ("We adopt the power factor requirement of 0.95 leading to 0.95 lagging because it is a common practice in some NERC regions. If a Transmission Provider wants to adopt a different power factor requirement, Final Rule LGIA Article 9.6.1 permits it to do so as long as the power factor requirement applies to all generators on a comparable basis.").

[92] *See, e.g.,* NaturEner Comments at 3 ("Based on the above technological and cost-based reasons, NaturEner believes the +/- 0.95 requirement is reasonable if the Proposed Rule is refined to measure the requirement at the wind turbine terminals (or as an alternative at the wind farm substation), and not at the Point of Interconnection.").

[93] Order No. 661, FERC Stats. & Regs. ¶ 31,186 at P 59.

[94] *Id.* P 66.

[95] *See ISO New England Inc.,* Tariff Filing, Transmittal Letter, Docket No. ER16–946–000, at 17 (filed Feb. 16, 2016) ("[T]he proposed requirements provide for the reactive capability to be measured at the high-side of the station transformer rather than at the Point of Interconnection to account for the long generator leads through which many wind generators are interconnecting to the New England system—as long as approximately 50–80 miles between the generator collector transformer and the Point of Interconnection. There is no benefit to the generator, and little benefit to the system, to force the generator to provide voltage support all the way to a Point of Interconnection that is very remote, and it is not necessarily even achievable to effectively transfer such quantities of reactive

fact, one of the reasons for undertaking this rulemaking proceeding was the Commission recognized that the cost of providing reactive power may no longer present an obstacle to the development of wind generation. On the other hand, measuring the reactive power requirements at the Generating Facilities would likely result in very little reactive power being provided to the transmission system but would be relatively inexpensive to implement for the non-synchronous generator. The high-side of the generator substation represents a middle ground. It is located beyond the low voltage collector systems where significant reactive power losses occur, resulting in more reactive power provided to the transmission system than a requirement at the Generating Facilities, while being less expensive to implement than a requirement at the Point of Interconnection. We find that measuring the reactive power requirements at the high-side of the generator substation reasonably balances the need for reactive power for the transmission system with the costs to non-synchronous generators of providing reactive power.

40. We find establishing dynamic reactive power requirements at the high-side of the generator substation preferable to the suggestion in the comments that, at relative equal cost, reactive power could be provided at the Point of Interconnection as long as the inherent dynamic reactive power produced by the generator can be enhanced with static reactive power capability. By establishing dynamic reactive power requirements at the high-side of the generator substation, non-synchronous generators will be able to provide faster responding and more continuously variable reactive power capability than if they provide static reactive power capability at the Point of Interconnection. In addition, requiring dynamic reactive power capability allows generators to operate across a broader range of operating conditions than allowing static reactive power enhancements.[96]

C. Real Power Output Level

1. NOPR Proposal

41. The NOPR proposed to require newly interconnecting non-synchronous generators to design their Generating Facilities to maintain the required power factor range only when the generator's real power output exceeds 10 percent of its nameplate capacity.[97] The proposed *pro forma* LGIA would state: "Non-synchronous generators shall only be required to maintain the above power factor when their output is above 10 percent of the Generating Facility Capacity." [98] The Commission stated its understanding that the inverters used by non-synchronous generators were not capable of producing reactive power when operating below 10 percent of nameplate capacity.[99]

2. Comments

42. Several commenters support the 10 percent exemption given current inverter technology.[100] EEI notes that the Commission uses both "generator nameplate capacity" and "Generator Facility Capacity" in reference to the 10 percent exemption, and requests that the Commission clarify that the correct term is "Generator Facility Capacity." [101] The ISO/RTO Council states that its ISO/RTO members do not uniformly agree that the 10 percent exemption is appropriate and want to be able to establish rules based on their individual situations.[102] Similarly, the Indicated NYTOs support the Commission allowing regional variation on the 10 percent exemption within a reasonable range based on existing regional requirements (up to an exemption for below 25 percent real power output).[103]

43. AWEA and LSA and the Joint NYTOs argue that the 10 percent exemption should be increased to 25 percent, consistent with what the Commission approved in PJM.[104] AWEA and LSA assert that the ability of non-synchronous generators to provide reactive power can be reduced when individual generators within the plant are not producing real power, such that the 10 percent operating threshold is insufficient.[105]

44. Other commenters oppose the 10 percent exemption, arguing that it is not necessary given the technology available to non-synchronous generators.[106] These commenters contend that some inverters can produce reactive power at zero real power output.[107] Additionally, ISO–NE argues that requiring non-synchronous generators to be capable of providing reactive power at all output levels will further technological development and advancement.[108] ISO–NE asserts that if the Commission adopts the 10 percent exemption, it should limit the exemption to only wind generators because non-synchronous generators other than wind generators have not had an exemption from the reactive power requirement and it is inappropriate to create a new exemption for these generators.[109]

45. MISO requests that non-synchronous generators be required to produce reactive power at low and zero-voltage conditions to ensure the robustness of the transmission system.[110] Similarly, Midwest Energy argues that the Commission has not fully considered the high levels of reactive power generated by lightly loaded interconnection facilities associated with non-synchronous generators.[111] Midwest Energy explains that its largest events of excess reactive power production have occurred when non-synchronous generators are producing less than 10 percent of their nameplate capacity. Midwest Energy asserts that it may be necessary for non-synchronous generators to install static inductors to absorb reactive power in these situations. Therefore, according to Midwest Energy, requiring non-synchronous generators to provide reactive power at all levels of real power output would prevent potential high voltage reliability concerns.[112]

46. AWEA and LSA request clarification regarding the proposal in the NOPR that non-synchronous generators be required to maintain a "composite power delivery at continuous rated power output at the Point of Interconnection at a power

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power over such distances."); *see also* NextEra Supplemental Comments at 3–4.

[96] EEI Comments at 8; ISO–NE Comments at 8; *see also ISO New England Inc.*, Tariff Filing, Transmittal Letter, Docket No. ER16–946–000, at 19 (filed Feb. 16, 2016) ("[I]n New England's experience, the implementation of the reactive power exemption has disadvantaged wind generators seeking to interconnect, putting burdens on the study process not experienced for conventional generators and compromising their ability to operate through various system conditions once interconnected, a situation that leads system operators to curtail wind farm output for system reliability reasons.").

[97] NOPR, FERC Stats. & Regs. ¶ 32,712 at P 15 (citing Order No. 661, FERC Stats. & Regs. ¶ 31,186 at P 46).

[98] *Id.* P 16. The Commission proposed similar revisions to the *pro forma* SGIA: "Non-synchronous generators shall only be required to maintain the above power factor when their output is above 10 percent of the generator nameplate capacity." *Id.*

[99] *Id.* P 15 (citing Order No. 661, FERC Stats. & Regs. ¶ 31,186 at P 46).

[100] EEI Comments at 9; NaturEner Comments at 4; NERC Comments at 10; SCE Comments at 3; NextEra Comments at 11.

[101] EEI Comments at 9–10.

[102] ISO/RTO Council Comments at 3.

[103] Indicated NYTOs Comments at 4.

[104] AWEA and LSA Comments at 13; Joint NYTOs Comments at 3.

[105] AWEA and LSA Comments at 13.

[106] ISO–NE Comments at 13; Midwest Energy Comments at 9; MISO Comments at 3.

[107] ISO–NE Comments at 14; NaturEner Comments at 4.

[108] ISO–NE Comments at 14.

[109] *Id.* at 14–15.

[110] MISO Comments at 3.

[111] Midwest Energy Comments at 2–3.

[112] *Id.* at 8.

factor within the range of 0.95 leading to 0.95 lagging."[113] AWEA and LSA argue that this language can be interpreted as either requiring non-synchronous generators to provide reactive power proportionate to the actual output of the generator, or to provide reactive power within the full power factor range based on the maximum output of the generator no matter the actual output of the generator.[114] AWEA and LSA contend that the first interpretation—a reactive power requirement proportionate to actual output—is the most reasonable interpretation.[115] NERC asserts that the second interpretation is correct.[116]

3. Commission Determination

47. We will not adopt the 10 percent exemption proposed in the NOPR in this Final Rule and will instead require all newly interconnecting non-synchronous generators to design their Generating Facilities to meet the reactive power requirements at all levels of real power output, as is already required of synchronous generators.[117] Although several commenters support the 10 percent exemption,[118] and some commenters support increasing that threshold to 25 percent,[119] we find, on balance, that requiring non-synchronous generators to provide reactive power at all levels of real power output appropriately recognizes the capabilities of existing non-synchronous generation technologies and creates requirements that are comparable to the existing requirement for synchronous generators. Additionally, by maintaining the reactive power requirement at all output levels, non-synchronous generators will mitigate potential over-voltage concerns on lightly loaded Interconnection Customer Interconnection Facilities of a non-synchronous generator when operating at low real power output.

48. While some commenters argue that technical limitations exist that prevent non-synchronous generators from providing adequate reactive power at lower levels of real power output, and note that the Commission approved a 25 percent exemption in PJM, several commenters indicate that non-synchronous generators *are* capable of providing reactive power at all levels of real power output.[120] Although the Commission approved a 25 percent exemption in PJM, that was pursuant to a section 205 filing with broad stakeholder support. We now act on a more comprehensive record and take action generically to apply to all transmission providers.[121] Moreover, while not all non-synchronous generators are currently designed to maintain reactive power capability at all levels of real power output, modern inverters can be designed to provide this capability. We agree with ISO–NE's comments that imposing this requirement will help encourage further technological development, such that the bulk power system will ultimately receive higher quality and more reliable reactive power service from all generators.

49. As for AWEA and LSA's and NERC's requested clarifications, we clarify that the amount of reactive power required from non-synchronous generators should be proportionate to the actual output of the generator, such that a 100 MW generator would be required to provide approximately 33 MVAR of reactive power when operating at maximum output (100 MW), and approximately 3.3 MVAR when operating at 10 MW, and so on. This addresses some commenters' concerns that sometimes not all non-synchronous generators at a particular location are operating at a given time (*e.g.*, only 50 of 100 wind turbines are actually spinning or ⅓ of solar panels are covered by clouds), without creating an unnecessary exemption for non-synchronous generators.

D. Compensation

1. NOPR Proposal

50. The Commission stated in the NOPR that non-synchronous generators are eligible for the same payments for reactive power as all other generators, consistent with the compensation provisions of the *pro forma* LGIA and *pro forma* SGIA.[122] The Commission proposed that any compensation for such non-synchronous generators would be based on the cost of providing reactive power, but noted that the cost to a wind generator of providing reactive power may not be easily estimated using existing methods that are applied to synchronous generators.[123] Therefore, the Commission sought comment on whether these existing methods are appropriate for wind generators and, if not, what alternatives would be appropriate.[124]

2. Comments

51. Several commenters support the Commission's proposal to require transmission providers to compensate non-synchronous generators for reactive power on a comparable basis as synchronous generators, provided that non-synchronous generators provide comparable reactive power service.[125] Other commenters seek clarification, or ask that the Commission outline principles for compensation.[126] Other commenters argue that the Commission should not mandate a uniform approach to reactive power compensation.[127] Finally, while some commenters ask that the Commission address the issue of reactive power compensation, they assert that addressing reactive power compensation in this rulemaking is outside the scope of the proceeding.[128]

3. Commission Determination

52. We will not change the Commission's existing policies on compensation for reactive power. Sections 9.6.3 and 11.6 of the currently-effective *pro forma* LGIA and sections 1.8.2 and 1.8.3 of the currently-effective *pro forma* SGIA provide that the transmission provider must compensate the interconnecting generator for reactive power service when the transmission provider requests that the interconnecting generator operate outside of the specified reactive power range. These sections also provide that if the transmission provider

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[113] AWEA and LSA Comments at 5; NOPR, FERC Stats. & Regs. ¶ 32,712 at P 16.

[114] AWEA and LSA Comments at 5–7 (explaining that the first interpretation will result in a triangular PQ curve, while the latter will result in a rectangular PQ curve); *see also* NERC Comments at 9.

[115] AWEA and LSA Comments at 6.

[116] NERC Comments at 9.

[117] Section 9.6.1 of the *pro forma* LGIA and section 1.8.1 of the *pro forma* SGIA.

[118] EEI Comments at 9; NaturEner Comments at 4; NERC Comments at 10; SCE Comments at 3; NextEra Comments at 11.

[119] AWEA and LSA Comments at 13; Joint NYTOs Comments at 3.

[120] ISO–NE Comments at 13; Midwest Energy Comments at 9; MISO Comments at 3.

[121] As discussed below, to the extent an ISO or RTO seeks to maintain an existing exemption, it can include such a request in its compliance filing as an independent entity variation and the Commission will consider the request at that time based on the arguments provided.

[122] NOPR, FERC Stats. & Regs. ¶ 32,712 at P 12 (citing Order No. 2003–A, FERC Stats. & Regs. ¶ 31,160 at P 416); *see also* sections 9.6.3 and 11.6 of the *pro forma* LGIA and sections 1.8.2 and 1.8.3 of the *pro forma* SGIA.

[123] NOPR, FERC Stats. & Regs. ¶ 32,712 at P 12 (citing *Payment for Reactive Power*, Commission Staff Report, Docket No. AD14–7, app. 2 (Apr. 22, 2014)).

[124] *Id.* P 18 (citation omitted).

[125] CAISO Comments at 9; EEI Comments at 10; ISO/RTO Council Comments at 7; MISO Comments at 3–4.

[126] ISO/RTO Council Comments at 7; SDG&E Comments at 4–5; AWEA and LSA Comments at 2–5; Public Interest Organizations Comments at 2–3; NextEra Comments at 14.

[127] Indicated NYTOs Comments at 4; ISO/RTO Council Comments at 7; SDG&E Comments at 4; CAISO Comments at 8–9; Joint NYTOs Comments at 4; SCE Comments at 3; Six Cities Comments at 2, 5–6.

[128] EPSA Comments at 6; NextEra Comments at 14.

compensates its own or affiliated generators for reactive power service within the specified reactive power range, it must compensate all generators for this service, and at what rate such compensation should be provided. While the Commission asked for comments on principles for compensating non-synchronous generators for reactive power, the comments, aside from noting that the current *AEP* methodology[129] does not translate to non-synchronous generation, did not provide a sufficient record for determining a new method. Therefore, any non-synchronous generator seeking reactive power compensation would need to propose a method for calculating that compensation as part of its filing. We note, however, that Commission staff is convening a workshop to explore reactive power compensation issues in the markets operated by ISOs/RTOs on June 30, 2016.[130]

E. Application of the Final Rule

1. NOPR Proposal

53. As a transition mechanism, the Commission proposed in the NOPR to apply the reactive power requirements in this Final Rule to all newly interconnecting non-synchronous generators that, as of the effective date of this Final Rule, either: (1) Have not executed an interconnection agreement; or (2) requested that an interconnection agreement be filed unexecuted that is still pending before the Commission. The Commission also proposed to apply the reactive power requirements to all existing non-synchronous generators making upgrades that require new interconnection requests after the effective date of the Final Rule. The Commission stated that it did not believe it would be reasonable or necessary to require all existing wind generators to provide reactive power because not all such generators are capable of providing reactive power without incurring substantial costs to install new equipment. However, the Commission proposed to require existing wind generators that make upgrades that require new interconnection requests to conform to the new reactive power requirements.[131]

2. Comments

54. CAISO and MISO support the Commission's proposed application of the new reactive power requirements to new and existing non-synchronous generators.[132] CAISO contends that interconnection customers should be required to adhere to the conditions of interconnection at the time they execute an interconnection agreement. CAISO states that, in its own reactive power stakeholder initiative, it proposed to apply a new reactive power requirement to its April 2016 interconnection queue cluster and to all future clusters. CAISO explains that, depending on the timing of the Final Rule, the new reactive power requirements would apply to this same group of interconnecting generators because they will not execute their interconnection agreements for at least one year after the study process begins. CAISO states that applying reactive power requirements to these interconnecting generators would ensure these generators do not lean on existing generators to provide reactive power.[133]

55. In contrast, some commenters argue that the Commission should not apply the new reactive power requirements to generators that have begun or have already received their System Impact Study, depending on the requirements of the Final Rule.[134] AWEA and LSA contend that applying the proposed reactive power requirements to non-synchronous generators that have begun their System Impact Study, or that have been in the interconnection queue for some period of time without starting their System Impact Study, may result in sizable costs and fundamental unfairness. AWEA and LSA argue that such non-synchronous generators may not have been designed to meet the new reactive power requirements and, therefore, may incur substantial equipment costs to meet those requirements.[135]

56. NextEra argues that the proposed application of the Final Rule to non-synchronous generators that have not yet executed an interconnection agreement is unreasonable if the Commission requires fully dynamic reactive power capability measured at the Point of Interconnection.[136] NextEra asserts that requiring fully dynamic reactive power capability at the Point of Interconnection would be a significant change to the status quo and would render some investments made by non-synchronous generators that have already received the results of their System Impact Study, but have not yet executed an interconnection agreement, useless. According to NextEra, such a major shift could also impose delays and additional costs related to the redesign, purchase, and installation of additional equipment.[137] NextEra contends that if the Commission allows for the use of static reactive power devices to supplement the dynamic reactive power capability of non-synchronous generators at the Point of Interconnection, the Commission would merely be formalizing what is already common practice, and, therefore, that the proposed application of the Final Rule would be reasonable. However, if the Commission requires fully dynamic reactive power capability at the Point of Interconnection, NextEra asks that the Final Rule not apply to non-synchronous generators that have received their System Impact Study.[138]

57. Some commenters also oppose the Commission's proposal to apply the reactive power requirements to existing non-synchronous generators making upgrades that require new interconnection requests.[139] AWEA and LSA assert that most upgrades do not involve fundamental changes to the original technology, or to the hardware, but instead simply involve software upgrades.[140] Lincoln argues that applying the new reactive power requirements to wind generators making upgrades could result in financial detriment to entities that have previously entered into binding contracts to purchase wind generation by exposing those entities to unforeseen expenses not contemplated when they entered into the contracts.[141] AWEA and LSA request that the new reactive power requirements only apply to upgrades on a case-by-case basis, depending on the outcome of the relevant interconnection study, and only to the incremental capacity requested through the upgrade.[142] AWEA and LSA also request that the Commission clarify what constitutes a "Material change" to a generator that would trigger a new interconnection study.[143]

58. SDG&E requests that the Commission clarify that the proposed

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[129] *See Am. Elec. Power Serv. Corp.*, Opinion No. 440, 88 FERC ¶ 61,141, at 61,456–57 (1999).

[130] *See Reactive Supply Compensation in Markets Operated by Regional Transmission Organizations and Independent System Operators*, Notice of Workshop, Docket No. AD16–17–000 (issued Mar. 17, 2016).

[131] NOPR, FERC Stats. & Regs. ¶ 32,712 at P 17.

[132] CAISO Comments at 5–6; MISO Comments at 5–6.

[133] CAISO Comments at 5–6.

[134] AWEA and LSA Comments at 14; NextEra Comments at 13.

[135] AWEA and LSA Comments at 14–15.

[136] NextEra Comments at 11.

[137] *Id.* at 12–13.

[138] *Id.* at 12.

[139] AWEA and LSA Comments at 14; Lincoln Comments at 2.

[140] AWEA and LSA Comments at 14.

[141] Lincoln Comments at 2.

[142] AWEA and LSA Comments at 14–15.

[143] *Id.* at 15.

reactive power requirements would apply to *all* non-synchronous generators and not to just wind generators.[144]

3. Commission Determination

59. We will apply the requirements of this Final Rule to all newly interconnecting non-synchronous generators that have not yet executed a Facilities Study Agreement[145] as of the effective date of this Final Rule. We will not apply the requirements of this Final Rule to existing non-synchronous generators making upgrades to their Generating Facilities that require new interconnection requests. However, such a generator may be required to provide reactive power if a transmission provider determines through that generator's System Impact Study that a reactive power requirement is necessary to ensure safety or reliability. The transition mechanism we establish in this Final Rule allows non-synchronous generators currently in the process of interconnecting to complete the interconnection process without unreasonable delay or expense.

a. Newly Interconnecting Non-Synchronous Generators

60. While the Commission proposed in the NOPR to apply the requirements of the Final Rule to all newly interconnecting non-synchronous generators that have not yet executed an interconnection agreement as of the effective date of the Final Rule, or requested that one be filed unexecuted that is still pending, we agree with AWEA and LSA, and NextEra,[146] that applying the Final Rule as proposed may unduly burden non-synchronous generators that have completed their System Impact Study. Such non-synchronous generators may have already purchased equipment needed to interconnect prior to executing an interconnection agreement (or requesting that one be filed unexecuted that is still pending).[147] We are especially concerned with applying new reactive power requirements to non-synchronous generators that have advanced in the interconnection process in light of our decision to measure the reactive power requirements at the high-side of the generator substation, rather than at the Point of Interconnection. Because the Point of Interconnection has been the industry standard under Appendix G to the *pro forma* LGIA, non-synchronous generators that have completed their System Impact Study may have relied on that standard in designing their Generating Facilities, thereby creating an undue burden on such generators.[148]

61. To avoid these undue burdens, we will apply the requirements of this Final Rule to all newly interconnecting non-synchronous generators that have not yet executed a Facilities Study Agreement as of the effective date of this Final Rule. Pursuant to the *pro forma* Large Generator Interconnection Procedures and to the *pro forma* Small Generator Interconnection Procedures, and simultaneous with the delivery of the System Impact Study, the transmission provider provides a draft Facilities Study Agreement to an interconnecting generator.[149] The executing of the Facilities Study Agreement immediately follows the completion of the System Impact Study. The execution of the Facilities Study Agreement, and the subsequent completion of the Facilities Study, represents the time in the interconnection process when the transmission provider and generator developer agree to the general technical requirements that will be needed for the generator to reliably interconnect to the transmission system.[150] This point in the interconnection process is early enough in the development of a generation project such that the project developer likely has not purchased equipment to interconnect their project because they have not yet reached an agreement with the transmission provider on the interconnection requirements of the project, which occurs after the completion of the System Impact Study. In choosing to apply the reactive power requirements of this Final Rule to projects that have not executed a Facilities Study Agreement, the Commission is ensuring that a majority of newly interconnecting non-synchronous generators are subject to the requirements of this Final Rule without subjecting projects to additional costs after the interconnection requirements of the project have been established.[151] Further, as discussed in the Commission's determination in Section III.B, *Power Factor Range, Point of Measurement, and Dynamic Reactive Power Capability Requirements,* the new reactive power requirement for non-synchronous generators will be measured at the high-side of the generator substation and should not result in the increased costs of providing dynamic reactive power at the Point of Interconnection that would substantially affect the financial viability of a non-synchronous generator in the interconnection queue that AWEA and LSA raise in their comments.

62. In addition, using the execution of a Facilities Study Agreement as the point in the interconnection process for transitioning to the requirements of this Final Rule represents a clearly defined point to avoid confusion in applicability. To further ensure clarity for newly interconnecting non-synchronous generators, we include in the revisions to section 9.6.1 to the *pro forma* LGIA and section 1.8.1 to *pro*

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[144] SDG&E Comments at 1, 3.

[145] The *pro forma* Large Generator Interconnection Procedures contain a standard "Interconnection Facilities Study Agreement" as Appendix 4. Similarly, the *pro forma* Small Generator Interconnection Procedures contain a standard "Facilities Study Agreement" as Attachment 8.

[146] AWEA and LSA Comments at 14; NextEra Comments at 13.

[147] AWEA and LSA explain that many non-synchronous generators will have already chosen their collector array cable and transformer or inverter before receiving an interconnection agreement. Rather than being able to choose equipment that could reduce reactive losses, the only compliance option for non-synchronous generators that are "significantly advanced" in the interconnection process to meet the requirements of the Final Rule would be to install potentially expensive reactive power devices. AWEA and LSA Comments at 15.

[148] NextEra Comments at 12–13.

[149] Section 8.1 of the *pro forma* Large Generator Interconnection Procedures state that, simultaneous with the delivery of the System Impact Study, the transmission provider must provide the interconnection customer with an Interconnection Facilities Study Agreement. Likewise, section 3.5 of the *pro forma* Small Generator Interconnection Procedures state that a transmission provider must provide an interconnection customer a Facilities Study Agreement along with the completed System Impact Study report.

[150] Section 7.3 of the *pro forma* Large Generator Interconnection Procedures explains that the System Impact Study will "provide the requirements or potential impediments to providing the requested interconnection service, including a preliminary indication of the cost and length of time that would be necessary to correct any problems identified in those analyses and implement the interconnection," along with "a list of facilities that are required as a result of the Interconnection Request and a non-binding good faith estimate of cost responsibility and a non-binding good faith estimated time to construct." Section 5.0 of the System Impact Study Agreement attached to the *pro forma* Small Generator Interconnection Procedures as Attachment 7 provides the same.

[151] *See, e.g., Neptune Regional Transmission Sys., LLC* v. *PJM Interconnection, L.L.C.,* 110 FERC ¶ 61,098, at P 23 ("Each customer knows that subsequent cost allocations will be determined by circumstances that are known as of the time its System Impact Study is conducted. Projects may drop out of the queue and customers may move up the queue, but the cost allocation system insulates an interconnection customer from costs arising from events occurring after its System Impact Study is completed, other than costs arising from changes from higher-queued generators. . . . If an interconnection customer were to be held financially responsible for the costs of events occurring after its System Impact Study is completed it would be impossible for the customer to make reasoned business decisions."), *order on reh'g,* 111 FERC ¶ 61,455 (2005), *aff'd sub nom. Pub. Serv. Elec. and Gas Co.* v. *FERC,* 485 F.3d 1164 (D.C. Cir. 2007).

forma SGIA this transition mechanism,[152] which we require transmission providers to adopt, as part of their compliance with this Final Rule.[153]

63. We also amend Appendix G to the *pro forma* LGIA, which public utility transmission providers are required to adopt, as part of their compliance with this Final Rule. Appendix G to the *pro forma* LGIA applies only to wind generators.[154] Those newly interconnecting wind generators that have executed a Facilities Study Agreement as of the effective date of this Final Rule will be subject to the amended Appendix G.[155] If Appendix G is not applicable to any newly interconnecting wind generators, the public utility transmission provider or RTO/ISO should remove Appendix G from its LGIA as part of its compliance filing. When all newly interconnecting wind generators that have executed Facilities Study Agreements as of the effective date of this Final Rule finalize their LGIAs and Appendix G is no longer necessary, we encourage the public utility transmission providers and RTOs/ISOs to file, or to include as part of, an FPA section 205 filing a proposal to remove Appendix G from their LGIA.

b. Upgrades to Existing Non-Synchronous Generators

64. Some commenters raise concerns with applying the requirements of this Final Rule to existing non-synchronous generators making upgrades that require new interconnection requests.[156] Generally, such generators would otherwise be exempt from the reactive power requirement. Lincoln argues that the proposed application of the new reactive power requirements to existing non-synchronous generators making upgrades could expose entities with existing power purchase agreements to unforeseen expenses.[157] As noted by AWEA and LSA, most upgrades that require new interconnection requests do not involve fundamental changes to the original technology, or to the hardware, but instead simply involve software upgrades.[158]

65. We recognize that there are a variety of triggering points for a new interconnection request in the various transmission provider regions, and the fact that an existing non-synchronous generator making an upgrade may not be installing new equipment. We also acknowledge, as the Commission did in the NOPR, that not all existing wind generators are capable of providing reactive power without incurring substantial costs to install new equipment.[159] Therefore, we will not apply the requirements of this Final Rule to existing non-synchronous generators making upgrades that require new interconnection requests.[160] Rather, we will maintain the existing approach in Appendix G to the *pro forma* LGIA for existing non-synchronous generators making upgrades to their Generating Facilities that require new interconnection requests after the effective date of this Final Rule, meaning that those upgrades will be exempt from the requirement to provide reactive power unless the transmission provider's System Impact Study shows that provision of reactive power by that generator is necessary to ensure safety or reliability.

66. We decline AWEA and LSA's request that the reactive power requirement apply only to the incremental capacity that results from an upgrade in the event the System Impact Study shows the need for reactive power.[161] If a transmission provider's System Impact Study shows the need for reactive power as a result of an upgrade, the transmission provider should have the flexibility to require reactive power capability consistent with the needs identified in the study, including the ability to apply the reactive power requirements of this Final Rule to all of the generator's capacity. Otherwise, allowing a transmission provider to apply the reactive power requirements only to the incremental capacity that results from an upgrade would undermine the Commission's goal of ensuring adequate reactive power support for the transmission system.[162] Therefore, we will give transmission providers the flexibility to apply the reactive power requirements to all of an existing non-synchronous generator's capacity when that generator makes an upgrade that requires a new interconnection request, and the System Impact Study shows the need for reactive power.[163]

67. We require transmission providers to propose, as part of their compliance with this Final Rule, tariff revisions implementing the transition mechanism laid out above for existing non-synchronous generators making upgrades to their Generating Facilities that require new interconnection requests.

F. Regional Flexibility

68. Multiple commenters request that the Commission recognize independent entity variations for ISOs/RTOs and regional differences for transmission providers outside of ISOs/RTOs in evaluating compliance with the Final Rule.[164]

69. We apply here all three of the methods for proposing variations adopted in Order No. 2003: (1) Variations based on Regional Entity reliability requirements; (2) variations that are "consistent with or superior to" the Final Rule; and (3) "independent

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[152] *See infra* P 74 (providing the amended text of section 9.6.1 to the *pro forma* LGIA and section 1.8.1 to the *pro forma* SGIA).

[153] In *West Deptford Energy, LLC* v. *FERC*, 766 F.3d 10, 20 (D.C. Cir. 2014), the court explained that the tariff provisions in effect at the time an interconnection agreement is executed apply to that interconnection customer, "unless the amended tariff has a grandfathering provision."

[154] *See* Order No. 661, FERC Stats. & Regs. ¶ 31,186, Appendix B (Appendix G—Interconnection Requirements for a Wind Generating Plant).

[155] *See infra* P 74 (providing the amended text of paragraph A.ii of Appendix G to the *pro forma* LGIA).

[156] AWEA and LSA Comments at 14; Lincoln Comments at 2.

[157] Lincoln Comments at 2.

[158] AWEA and LSA Comments at 14.

[159] NOPR, FERC Stats. & Regs. ¶ 32,712 at P 17.

[160] Given our determination not to adopt the NOPR proposal, we find moot AWEA and LSA's request that the Commission clarify what constitutes a "Material change" to a generator that would trigger a new interconnection study. We note that, on May 13, 2016, Commission staff held a technical conference on generator interconnection issues, exploring triggers for restudies, among other things. *See Review of Generator Interconnection Agreements and Procedures*, Supplemental Notice of Technical Conference, Docket Nos. RM16–12–000, RM15–21–000 (issued May 4, 2016); *Review of Generator Interconnection Agreements and Procedures*, Notice Inviting Post-Technical Conference Comments, Docket Nos. RM16–12–000, RM15–21–000 (issued June 3, 2016) (Question 1.10: "Should interconnection procedures be more specific about what constitutes a material modification to a generator interconnection request? Is it clear to interconnection customers what types of modifications to their interconnection requests would and would not affect their place in the queue? Do transmission owners and RTO/ISOs exercise any level of discretion in determining whether a customer has made a material modification? What is the range and nature of that discretion? Please reference provisions in interconnection procedures, as applicable, in your answer.").

[161] AWEA and LSA Comments at 14–15.

[162] NOPR, FERC Stats. & Regs. ¶ 32,712 at P 11 (explaining the Commission's concern that the growing penetration of wind generators increases the potential for a deficiency in reactive power, and resulting local reliability issues).

[163] As with the existing approach, should an existing non-synchronous generator disagree with the transmission provider that the System Impact Study shows a need for reactive power as a result of the upgrade, it may challenge the transmission provider's conclusion through dispute resolution or appeal to the Commission. *See* Order No. 661, FERC Stats. & Regs. ¶ 31,186 at P 51.

[164] EEI Comments at 11; Indicated NYTOs Comments at 3; ISO–NE Comments at 11–12; ISO/RTO Council Comments at 3; Joint NYTOs Comments at 3; NEPOOL Initial Comments at 6; NEPOOL Supplemental Comments at 3–4.

entity variations" from ISOs/RTOs.[165] If a transmission provider seeks to justify variations from the requirements of this Final Rule, it may do so in its compliance filing. A transmission provider may propose to include standards developed by NERC or a Regional Entity in its own standard interconnection agreement. The Commission is mindful of the work being done by these organizations in developing standards for the interconnection of non-synchronous generators, and we strongly encourage all interested parties to continue to participate in developing these standards.

G. Miscellaneous Comments

70. CAISO argues that the Commission should allow transmission providers to propose additional technical requirements for interconnecting non-synchronous generators related to voltage support, such as requiring automatic voltage control.[166] Transmission providers may propose additional technical requirements, to the extent they believe those are necessary, in a separate filing pursuant to section 205 of the FPA.

71. MATL requests clarification that the Commission will continue to accept tariff arrangements that require customers on merchant transmission lines to self-supply ancillary services. MATL specifically requests that this clarification be included in the final rule compliance obligation, and in similar future proceedings.[167] We clarify that merchant transmission lines that have received exemptions from providing ancillary services will not be affected by this Final Rule. Therefore, those entities that do not have reactive power requirements in their Commission-approved OATTs will not need to submit a compliance filing in response to this Final Rule.

72. SCE requests that the Commission expand the scope of the rulemaking proceeding to include low voltage ride-through requirements for synchronous and non-synchronous Generating Facilities smaller than 20 MW.[168] We decline to expand the scope of the rulemaking proceeding to include low voltage ride-through requirements for synchronous and non-synchronous Generating Facilities smaller than 20 MW. We note that the Commission has issued a Notice of Proposed Rulemaking, *Requirements for Frequency and Voltage Ride Through Capability of Small Generating Facilities,* to consider these issues.[169]

73. AWEA and LSA request that the Commission limit the reactive power requirements to a specific range of voltage at the Point of Interconnection.[170] NERC also recommends that the Commission clarify the reactive power requirements by providing a reactive capability versus voltage characteristic diagram.[171] We find the request to specify a voltage range for the reactive power requirements to be outside the scope of this proceeding. The existing *pro forma* LGIA and *pro forma* SGIA do not specify a voltage range for the reactive power requirement for synchronous generators, and the Commission does not have a sufficient record on which to create such a requirement.

IV. Compliance and Implementation

74. Section 35.28(f)(1) of the Commission's regulations requires every public utility with a non-discriminatory OATT on file to also have on file the *pro forma* LGIA and *pro forma* SGIA "required by Commission rulemaking proceedings promulgating and amending such interconnection procedures and agreements." [172] The Commission hereby revises section 9.6.1 of the *pro forma* LGIA to read:

> 9.6.1 Power Factor Design Criteria
>
> *9.6.1.1 Synchronous Generation.* Interconnection Customer shall design the Large Generating Facility to maintain a composite power delivery at continuous rated power output at the Point of Interconnection at a power factor within the range of 0.95 leading to 0.95 lagging, unless *the* Transmission Provider has established different requirements that apply to all *synchronous* generators in the Control Area on a comparable basis. [The requirements of this paragraph shall not apply to wind generators.] (Bracketed text is deleted.)
>
> *9.6.1.2 Non-Synchronous Generation. Interconnection Customer shall design the Large Generating Facility to maintain a composite power delivery at continuous rated power output at the high-side of the generator substation at a power factor within the range of 0.95 leading to 0.95 lagging, unless the Transmission Provider has established a different power factor range that applies to all non-synchronous generators in the Control Area on a comparable basis. This power factor range standard shall be dynamic and can be met using, for example, power electronics designed to supply this level of reactive capability (taking into account any limitations due to voltage level, real power output, etc.) or fixed and switched capacitors, or a combination of the two. This requirement shall only apply to newly interconnecting non-synchronous generators that have not yet executed a Facilities Study Agreement as of the effective date of the Final Rule establishing this requirement (Order No. 827).*

The Commission similarly revises section 1.8.1 of the *pro forma* SGIA to read:

> 1.8.1 *Power Factor Design Criteria*
>
> *1.8.1.1 Synchronous Generation.* The Interconnection Customer shall design its Small Generating Facility to maintain a composite power delivery at continuous rated power output at the Point of Interconnection at a power factor within the range of 0.95 leading to 0.95 lagging, unless the Transmission Provider has established different requirements that apply to all similarly situated *synchronous* generators in the control area on a comparable basis. [The requirements of this paragraph shall not apply to wind generators.] (Bracketed text is deleted.)
>
> *1.8.1.2 Non-Synchronous Generation. The Interconnection Customer shall design its Small Generating Facility to maintain a composite power delivery at continuous rated power output at the high-side of the generator substation at a power factor within the range of 0.95 leading to 0.95 lagging, unless the Transmission Provider has established a different power factor range that applies to all similarly situated non-synchronous generators in the control area on a comparable basis. This power factor range standard shall be dynamic and can be met using, for example, power electronics designed to supply this level of reactive capability (taking into account any limitations due to voltage level, real power output, etc.) or fixed and switched capacitors, or a combination of the two. This requirement shall only apply to newly interconnecting non-synchronous generators that have not yet executed a Facilities Study Agreement as of the effective date of the Final Rule establishing this requirement (Order No. 827).*

In addition, the Commission revises paragraph A.ii of Appendix G to the *pro forma* LGIA, "Technical Standards Applicable to a Wind Generation Plant," as follows: [173]

> *The following reactive power requirements apply only to a newly interconnecting wind generating plant that has executed a Facilities Study Agreement as of the effective date of the Final Rule establishing the reactive power requirements for non-*

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[165] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at PP 824–827; *see also* Order No. 661, FERC Stats. & Regs. ¶ 31,186 at P 109.

[166] CAISO Comments at 8.

[167] MATL Comments at 5.

[168] SCE Comments at 4.

[169] *See Requirements for Frequency and Voltage Ride Through Capability of Small Generating Facilities,* Notice of Proposed Rulemaking, 81 FR 15481 (Mar. 23, 2016), 154 FERC ¶ 61,222 (2016).

[170] AWEA and LSA Comments at 7 (explaining the range of voltage and providing a proposed Q–V curve).

[171] NERC Comments at 9–10.

[172] 18 CFR 35.28(f)(1) (2015).

[173] The full text of the *pro forma* LGIA will be posted on the Commission's internet page at: *http://www.ferc.gov/industries/electric/indus-act/gi/stnd-gen.asp.* The full text of the *pro forma* SGIA will be posted on the Commission's internet page at: *http://www.ferc.gov/industries/electric/indus-act/gi/small-gen.asp.*

> *synchronous generators in section 9.6.1 of this LGIA (Order No. 827).* A wind generating plant *to which this provision applies* shall maintain a power factor within the range of 0.95 leading to 0.95 lagging, measured at the Point of Interconnection as defined in this LGIA, if the Transmission Provider's System Impact Study shows that such a requirement is necessary to ensure safety or reliability. The power factor range standard can be met by using, for example, power electronics designed to supply this level of reactive capability (taking into account any limitations due to voltage level, real power output, etc.) or fixed and switched capacitors if agreed to by the Transmission Provider, or a combination of the two. The Interconnection Customer shall not disable power factor equipment while the wind plant is in operation. Wind plants shall also be able to provide sufficient dynamic voltage support in lieu of the power system stabilizer and automatic voltage regulation at the generator excitation system if the System Impact Study shows this to be required for system safety or reliability.[174]

75. As in Order Nos. 2003[175] and 661,[176] the Commission is requiring all public utility[177] transmission providers to adopt the requirements of this Final Rule as revisions (as discussed above) to the LGIA and SGIA in their OATTs within 90 days after the publication of this Final Rule in the **Federal Register**.[178] Transmission providers that are not public utilities also must adopt the requirements of this Final Rule as a condition of maintaining the status of their safe harbor tariff or otherwise satisfying the reciprocity requirement of Order No. 888.[179] As discussed above, we are not requiring changes to interconnection agreements already in effect, but are applying the requirements of this Final Rule to newly interconnecting non-synchronous generators that have not yet executed a Facilities Study Agreement. The requirements of this Final Rule also do not apply to existing non-synchronous generators making upgrades to their Generating Facilities that require new interconnection requests.

76. In some cases, public utility transmission providers may have provisions in the currently effective LGIAs and SGIAs in their OATTs related to the provision of reactive power by non-synchronous generators that the Commission has deemed to be consistent with or superior to the *pro forma* LGIA and *pro forma* SGIA. Where the relevant provisions of the *pro forma* LGIA and *pro forma* SGIA are modified by this Final Rule, public utility transmission providers must either comply with this Final Rule or demonstrate that their previously-approved LGIA and SGIA variations continue to be consistent with or superior to the *pro forma* LGIA and *pro forma* SGIA as modified by this Final Rule.

77. In addition, some ISOs/RTOs may have provisions in the currently effective LGIAs and SGIAs in their OATTs related to the provision of reactive power by non-synchronous generators that the Commission has accepted as an independent entity variation to the *pro forma* LGIA and *pro forma* SGIA. Where the relevant provisions of the *pro forma* LGIA and *pro forma* SGIA are modified by this Final Rule, ISOs/RTOs must either comply with this Final Rule or demonstrate that their previously-approved LGIA and SGIA variations continue to justify an independent entity variation from the *pro forma* LGIA and *pro forma* SGIA as modified by this Final Rule.

V. Information Collection Statement

78. The following collection of information contained in this Final Rule is subject to review by the Office of Management and Budget (OMB) regulations under section 3507(d) of the Paperwork Reduction Act of 1995.[180] OMB's regulations require approval of certain information collection requirements imposed by agency rules.[181] Upon approval of a collection of information, OMB will assign an OMB control number and expiration date. Respondents subject to the filing requirements of this Final Rule will not be penalized for failing to respond to this collection of information unless the collection of information displays a valid OMB control number.

79. The reforms adopted in this Final Rule revise the Commission's *pro forma* LGIA and *pro forma* SGIA in accordance with section 35.28(f)(1) of the Commission's regulations.[182] This Final Rule requires each public utility transmission provider to revise its *pro forma* LGIA and *pro forma* SGIA to: (1) Eliminate the exemptions for wind generators from the requirement to provide reactive power; and (2) require that all newly interconnecting non-synchronous generators that have not yet executed a Facilities Study Agreement provide reactive power as a condition of interconnection as set forth in their LGIA or SGIA as of the effective date of this Final Rule. The reforms adopted in this Final Rule require filings of *pro forma* LGIAs and *pro forma* SGIAs with the Commission. The Commission anticipates the revisions required by this Final Rule, once implemented, will not significantly change currently existing burdens on an ongoing basis. With regard to those public utility transmission providers that believe that they already comply with the revisions adopted in this Final Rule, they can demonstrate their compliance in the filing required 90 days after the effective date of this Final Rule. The Commission will submit the proposed reporting requirements to OMB for its review and approval under section 3507(d) of the Paperwork Reduction Act.[183]

80. While the Commission expects the revisions adopted in this Final Rule will provide significant benefits, the Commission understands that implementation can be a complex and costly endeavor. The Commission solicited comments on the accuracy of provided burden and cost estimates and any suggested methods for minimizing the respondents' burdens. The Commission did not receive any comments concerning its burden or cost estimates. Therefore, the Commission retains the estimates proposed in the NOPR, with minor changes to reflect updated estimates.

Burden Estimate: The Commission believes that the burden estimates below are representative of the average burden on respondents. The estimated burden and cost for the requirements adopted in this Final Rule follow.[184]

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[174] Section A.ii of Appendix G to the *pro forma* LGIA.

[175] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 910.

[176] Order No. 661, FERC Stats. & Regs. ¶ 31,186 at P 121.

[177] For purposes of this Final Rule, a public utility is a utility that owns, controls, or operates facilities used for transmitting electric energy in interstate commerce, as defined by the FPA. *See* 16 U.S.C. 824(e) (2012). A non-public utility that seeks voluntary compliance with the reciprocity condition of an OATT may satisfy that condition by filing an OATT, which includes the *pro forma* LGIA and *pro forma* SGIA.

[178] MISO requests that the Commission extend the requirements of this Final Rule to the MISO *pro forma* Generator Interconnection Agreement and not just to the Commission's *pro forma* LGIA and *pro forma* SGIA. MISO Comments at 4–6. As stated, each public utility transmission provider subject to this Final Rule is directed to adopt the requirements of this Final Rule as revisions to the standard interconnection agreements in its OATT.

[179] Order No. 888, FERC Stats. & Regs. ¶ 31,036 at 31,760–63.

[180] 44 U.S.C. 3507(d) (2012).

[181] 5 CFR 1320.11 (2015).

[182] 18 CFR 35.28(f)(1) (2015).

[183] 44 U.S.C. 3507(d) (2012).

[184] Commission staff estimates that industry is similarly situated in terms of hourly cost (wages plus benefits). Based on the Commission's average cost (wages plus benefits) for 2015, $72/hour is used.

FERC 516B REVISIONS IN FINAL RULE IN RM16–1

	Number of respondents[185] (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden (hrs.) and cost ($) per response (4)	Total annual burden hours and total annual cost ($) (3) * (4) = (5)
Conforming LGIA changes to incorporate revisions.	132	1	132	7.5 $540	990 hours. $71,280.
Conforming SGIA changes to incorporate revisions.	118	1	118	7.5 $540	885 hours. $63,720.
Total			250	15 hours $1,080	1,875 hours. $135,000.

Cost to Comply: The Commission has projected the total cost of compliance as follows:[186]

- Year 1: $135,000 ($1,080/utility).
- Year 2: $0.

After implementation in Year 1, the revisions adopted in this Final Rule would be complete.

Title: FERC–516B, Electric Rate Schedules and Tariff Filings.

Action: Revisions to an information collection.

OMB Control No.: TBD

Respondents for this Rulemaking: Businesses or other for profit and/or not-for-profit institutions.

Frequency of Information: One-time during Year 1.

Necessity of Information: The Commission adopts revisions in this Final Rule to the *pro forma* LGIA and *pro forma* SGIA to improve the reliability of the bulk power system by requiring all newly interconnecting non-synchronous generators to provide reactive power as a condition of interconnection, and to ensure that all generators are being treated in a not unduly discriminatory or preferential manner.

Internal Review: The Commission has reviewed the requirements in this Final Rule and has determined that such revisions are necessary. These requirements conform to the Commission's need for efficient information collection, communication, and management within the energy industry. The Commission has assured itself, by means of internal review, that there is specific, objective support for the burden estimates associated with the information collection requirements.

81. Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director], email: *DataClearance@ferc.gov,* phone: (202) 502–8663, fax: (202) 273–0873.

82. Comments on the collection of information and the associated burden estimates in this Final Rule should be sent to the Commission in this docket and may also be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission], at the following email address: *oira_submission@omb.eop.gov.* Please reference the docket number of this rulemaking in your submission.

VI. Regulatory Flexibility Act Certification

83. The Regulatory Flexibility Act of 1980 (RFA)[187] generally requires a description and analysis of rules that will have significant economic impact on a substantial number of small entities. The RFA does not mandate any particular outcome in a rulemaking. It only requires consideration of alternatives that are less burdensome to small entities and an agency explanation of why alternatives were rejected.

84. The Small Business Administration (SBA) revised its size standards (effective January 22, 2014) for electric utilities from a standard based on megawatt hours to a standard based on the number of employees, including affiliates. Under SBA's standards, some transmission owners will fall under the following category and associated size threshold: Electric bulk power transmission and control, at 500 employees.[188]

85. The Commission estimates that the total number of public utility transmission providers that would have to modify the LGIAs and SGIAs within their currently effective OATTs is 132. Of these, the Commission estimates that approximately 43 percent are small entities (approximately 57 entities). The Commission estimates the average total cost to each of these entities will be minimal, requiring on average 15 hours or $1,080. According to SBA guidance, the determination of significance of impact "should be seen as relative to the size of the business, the size of the competitor's business, and the impact the regulation has on larger competitors."[189] The Commission does not consider the estimated burden to be a significant economic impact. As a result, the Commission certifies that the revisions adopted in this Final Rule will not have a significant economic impact on a substantial number of small entities.

VII. Environmental Analysis

86. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[190] As we stated in the NOPR, the Commission concludes that neither an Environmental Assessment nor an Environmental Impact Statement is required for the revisions adopted in this Final Rule under section 380.4(a)(15) of the Commission's

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[185] Number of Applicable Registered Entities.

[186] The costs for Year 1 consist of filing revisions to the *pro forma* LGIA and *pro forma* SGIA with the Commission within 90 days of the effective date of this Final Rule plus initial implementation. The Commission does not expect any ongoing costs beyond the initial compliance in Year 1.

[187] 5 U.S.C. 601–12 (2012).

[188] 13 CFR 121.201, Sector 22 (Utilities), NAICS code 221121 (Electric Bulk Power Transmission and Control) (2015).

[189] U.S. Small Business Administration, *A Guide for Government Agencies How to Comply with the Regulatory Flexibility Act,* at 18 (May 2012), *https://www.sba.gov/sites/default/files/advocacy/rfaguide_0512_0.pdf.*

[190] *Regulations Implementing National Environmental Policy Act of 1969,* Order No. 486, FERC Stats. & Regs. ¶ 30,783 (1987).

regulations, which provides a categorical exemption for approval of actions under sections 205 and 206 of the FPA relating to the filing of schedules containing all rates and charges for the transmission or sale of electric energy subject to the Commission's jurisdiction, plus the classification, practices, contracts and regulations that affect rates, charges, classifications, and services.[191] The revisions adopted in this Final Rule update and clarify the application of the Commission's standard interconnection requirements to non-synchronous generators. Therefore, this Final Rule falls within the categorical exemptions provided in the Commission's regulations, and as a result neither an Environmental Impact Statement nor an Environmental Assessment is required.

VIII. Document Availability

87. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

88. From the Commission's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number of this document, excluding the last three digits, in the docket number field.

89. User assistance is available for eLibrary and the Commission's Web site during normal business hours from the Commission's Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

IX. Effective Date and Congressional Notification

90. The Final Rule is effective September 21, 2016. However, as noted above, the requirements of this Final Rule will apply only to newly interconnecting non-synchronous generators that have not yet executed a Facilities Study Agreement. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this Final Rule is not a "major rule" as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996. This Final Rule is being submitted to the Senate, House, Government Accountability Office, and Small Business Administration.

List of Subjects in 18 CFR Part 35

Electric power rates, Electric utilities, Non-discriminatory open access transmission tariffs.

By the Commission.

Issued: June 16, 2016.

Kimberly D. Bose,

Secretary.

The following appendix will not appear in the Code of Federal Regulations.

APPENDIX A—LIST OF COMMENTERS

[RM16–1–000]

AWEA and LSA	American Wind Energy Association and Large-scale Solar Association.
CAISO	California Independent System Operator Corporation.
EEI	Edison Electric Institute.
EPSA	Electric Power Supply Association.
Idaho Power	Idaho Power Company.
Indicated NYTOs	Consolidated Edison Company of New York, Inc.; Niagara Mohawk Power Corporation d/b/a National Grid; and Orange and Rockland Utilities, Inc.
ISO/RTO Council	ISO/RTO Council.
ISO-NE	ISO New England Inc.
ITC	International Transmission Company d/b/a ITC Transmission; Michigan Electric Transmission Company, LLC; ITC Midwest LLC; and ITC Great Plains, LLC.
Joint NYTOs	New York Power Authority; New York State Electric and Gas; Rochester Gas and Electric; and Central Hudson Gas and Electric.
Lincoln	City of Lincoln, Nebraska d/b/a Lincoln Electric System.
MATL	MATL LLP.
Midwest Energy	Midwest Energy, Inc.
MISO	Midcontinent Independent System Operator, Inc.
NaturEner	NaturEner USA, LLC and its subsidiaries.
NEPOOL	New England Power Pool Participants Committee.
NERC	North American Electric Reliability Corporation.
NextEra	NextEra Energy, Inc.
PG&E	Pacific Gas and Electric Company.
Public Interest Organizations	Center for Rural Affairs; Clean Wisconsin; Great Plains Institute; Natural Resources Defense Council; Sierra Club; Sustainable FERC Project; Western Grid Group; Wind on the Wires.
SCE	Southern California Edison Company.
SDG&E	San Diego Gas and Electric Company.
Six Cities	Cities of Anaheim, Azusa, Banning, Colton, Pasadena, and Riverside, California.
Union of Concerned Scientists	Union of Concerned Scientists.

[FR Doc. 2016–14764 Filed 6–22–16; 8:45 am]

BILLING CODE 6717–01–P

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[191] 18 CFR 380.4(a)(15) (2015).

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9761]

RIN 1545–BM88

Inversions and Related Transactions; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations; correction.

SUMMARY: This document contains corrections to final and temporary regulations (TD 9761) that were published in the **Federal Register** on April 8, 2016 (81 FR 20858). The temporary regulations address transactions that are structured to avoid the purposes of sections 7874 and 367 of the Internal Revenue Code and certain post-inversion tax avoidance transactions.

DATES: This correction is effective on June 23, 2016 and applicable on April 8, 2016.

FOR FURTHER INFORMATION CONTACT: Rose E. Jenkins at (202) 317–6934 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations (TD 9761) that are the subject of this correction are under sections 304, 367, 956, 7701(l), and 7874 of the Internal Revenue Code.

Need for Correction

As published, the final and temporary regulations (TD 9761) contain errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the final and temporary regulations (TD 9761), that are the subject of FR Doc. 2016–07300, are corrected as follows:

1. On page 20858, in the preamble, the second column, the ninth line from the bottom of the column, the language "section 7874 and § 1.367(a)–3(c) and" is corrected to read "section 7874 and".
2. On page 20860, in the preamble, the third column, under the paragraph heading "*E. Section 7701*", the language "re-characterizing" and "re-characterization" is corrected to read "recharacterizing" and "recharacterization" respectively wherever it appears.
3. On page 20862, in the preamble, the third column, under the paragraph heading "a. § 1.7874–4T, In General" the fifth and sixth lines, the language "entity acquisition described in section 7874(a)(2)(B)(i) is excluded from the" is corrected to read "entity acquisition is excluded from the".
4. On page 20869, in the preamble, the first column, the twenty-fifth line from the bottom of the column, the language "60% or 80% on the completion date." is corrected to read "60 or 80 on the completion date.".
5. On page 20871, in the preamble, the second column, the third and tenth lines from the top of the first full paragraph, the language "domestic" is removed.
6. On page 20873, in the preamble, the third column, under the paragraph heading "*II. Rules Addressing Certain Post-Inversions Tax Avoidance Transactions*" the first line, the language "As stated in Section 1 of the 2014" is corrected to read "As stated in section 1 of the 2014".
7. On page 20874, in the preamble, the third column, the twenty-second line from the top of the column, the language "completion date, is treated as an" is corrected to read "completion date is treated as an".
8. On page 20877, in the preamble, the first column, under the paragraph heading "ii. Exceptions From Recharacterization" the twelfth line of the first full paragraph, the language "recognized. See Section 2.C of this Part" is corrected to read "recognized. See Section 2.c of this Part".
9. On page 20880, in the preamble, the first column, under the paragraph heading "b. Regulations Implementing the Section 367(b) Asset Dilution Rule" the third line from the bottom of the column, the language "property to a foreign transferee" is corrected to read "property to a transferee foreign".

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2016–14648 Filed 6–22–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9761]

RIN 1545–BM88

Inversions and Related Transactions; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations; correcting amendment.

SUMMARY: This document contains corrections to final and temporary regulations (TD 9761) that were published in the **Federal Register** on April 8, 2016 (81 FR 20858). The temporary regulations address transactions that are structured to avoid the purposes of sections 7874 and 367 of the Internal Revenue Code and certain post-inversion tax avoidance transactions.

DATES: This correction is effective on June 23, 2016 and applicable on April 8, 2016.

FOR FURTHER INFORMATION CONTACT: Rose E. Jenkins at (202) 317–6934 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations (TD 9761) that are the subject of this correction are under sections 304, 367, 956, 7701(l), and 7874 of the Internal Revenue Code.

Need for Correction

As published, the final and temporary regulations (TD 9761) contain errors that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.304–7T is amended by revising paragraph (f) to read as follows:

§ 1.304–7T Certain acquisitions by foreign acquiring corporations (temporary).

* * * * *

(f) *Expiration date.* This section expires on or before April 4, 2019.

■ **Par. 3.** Section 1.367(a)–3T is amended by revising paragraph (k) to read as follows:

§ 1.367(a)–3T Treatment of transfers of stock or securities to foreign corporations (temporary).

* * * * *

(k) *Expiration date.* Paragraph (c)(3)(iii)(C) of this section expires on or before April 4, 2019.

§ 1.367(b)–4 [Amended]

■ **Par. 4.** For each entry in § 1.367(b)–4 in the "Paragraph" column remove the language in the "Remove" column and add in its place the language in the "Add" column as set forth below:

Paragraph	Remove	Add
(b)(1)(i)(B)(*2*)	foreign acquiring corporation	transferee foreign corporation.
(b)(1)(ii)(A), first sentence	foreign acquiring corporation	transferee foreign corporation.
(b)(2)(i)(A)	foreign acquiring corporations	transferee foreign corporation.
(b)(2)(i)(B)	foreign acquiring corporation	transferee foreign corporation.
(b)(2)(i)(C)	foreign acquiring corporation	transferee foreign corporation.
(b)(3)(i)	foreign acquiring corporation	transferee foreign corporation.
(d)(2), Example, heading	foreign acquiring corporation	transferee foreign corporation.

§ 1.367(b)–4T [Amended]

■ **Par. 5.** Section 1.367(b)–4T(d)(1) is amended by removing the language "§ 1.367(b)–(3)" and adding in its place the language "§ 1.367(b)–3".

■ **Par. 6.** Section 1.956–2T is amended by revising the first sentence of paragraph (a)(4)(iii) *Example 3.*(A), the second sentence of paragraph (a)(4)(iii) *Example 3.*(B), and the third sentence of paragraph (a)(4)(iii) *Example 4.*(B) to read as follows:

§ 1.956–2T Definition of United States property (temporary).

* * * * *

(a) * * *

(4) * * *

(iii) * * *

Example 3. (A) *Facts.* Before the inversion transaction, FA also wholly owns USP, a domestic corporation, which, in turn, wholly owns, LFS, a foreign corporation that is a controlled foreign corporation. * * *

(B) * * * Because LFS was a controlled foreign corporation and a member of the EAG with respect to the inversion transaction on the completion date, and DT was not a United States shareholder with respect to LFS on or before the completion date, LFS is excluded from the definition of expatriated foreign subsidiary pursuant to § 1.7874–12T(a)(9)(ii). * * *

Example 4. * * *

(B) * * * Because LFSS was not a member of the EAG with respect to the inversion transaction on the completion date, LFSS is not excluded from the definition of expatriated foreign subsidiary pursuant to § 1.7874–12T(a)(9)(ii). * * *

* * * * *

■ **Par. 7.** Section 1.7701(l)–4T is amended by revising the ninth sentence of paragraph (a), the fourth sentence of paragraph (g) *Example 3.*(ii)(B), and the third sentence of paragraph (g) *Example 11.*(ii) to read as follows:

§ 1.7701(l)–4T Rules regarding inversion transactions (temporary).

(a) * * * See § 1.367(b)–4T(e) and (f) for rules concerning certain other exchanges after an inversion transaction. * * *

* * * * *

(g) * * *

Example 3. * * *

(ii) * * *

(B) * * * Although FA (a non-CFC foreign related person) indirectly owns $4x of FT stock both immediately before and after the specified transaction and any related transaction, all of that stock is directly owned by DT (a domestic corporation), and as a result, under paragraph (f)(4) of this section, none of that stock is treated as directly or indirectly owned by FP for purposes of calculating the pre-transaction ownership percentage and the post-transaction ownership percentage with respect to FT. * * *

* * * * *

Example 11. * * *

(ii) * * * However, after the April 30, 2016 transfer, because FS ceases to be a foreign related person, it ceases to be a specified related person. * * *

* * * * *

■ **Par. 8.** Section 1.7874–1T is amended by revising paragraph (i) to read as follows:

§ 1.7874–1T Disregard of affiliate-owned stock (temporary).

* * * * *

(i) *Expiration date.* This section expires on or before April 4, 2019.

■ **Par. 9.** Section 1.7874–2T is amended by revising paragraphs (c)(4)(iii) and (m) to read as follows:

§ 1.7874–2T Surrogate foreign corporation (temporary).

* * * * *

(c) * * *

(4) * * *

(iii) *Additional related transactions.* If, pursuant to the same plan (or a series of related transactions), a foreign corporation directly or indirectly acquires (under the principles of paragraph (c)(4)(ii) of this section) substantially all of the properties directly or indirectly held by a subsequent acquiring corporation in a transaction occurring after the subsequent acquisition, then the principles of paragraph (c)(4)(i) of this section apply to such transaction (and any subsequent transaction or transactions occurring pursuant to the plan (or the series of related transactions)).

* * * * *

(m) *Expiration date.* This section expires on or before April 4, 2019.

■ **Par. 10.** Section 1.7874–3T is amended by revising paragraph (g) to read as follows:

§ 1.7874–3T Substantial business activities (temporary).

* * * * *

(g) *Expiration date.* The applicability of paragraphs (b)(4) and (d)(10) of this section expires on or before April 4, 2019.

■ **Par. 11.** Section 1.7874–6T is amended by revising paragraphs (f)(3) and (i) to read as follows:

§ 1.7874–6T Stock transferred by members of the EAG (temporary).

* * * * *

(f) * * *

(3) A *transferring corporation* means a corporation that is a former domestic entity shareholder or former domestic entity partner.

* * * * *

(i) *Expiration date.* This section expires on or before April 4, 2019.

■ **Par. 12.** Section 1.7874–7T is amended by revising the first sentence of paragraph (g) *Example 2.*(ii) and paragraph (i) to read as follows:

§ 1.7874–7T Disregard of certain stock attributable to passive assets (temporary).

* * * * *

(g) * * *

Example 2. * * *

(ii) *Analysis.* Without regard to the application of §§ 1.7874–4T(b) and 1.7874–10T(b) and paragraph (b) of this section, the ownership percentage described in section 7874(a)(2)(B)(ii) would be less than 5 (by vote and value), or 4 (4/100, or 4 shares of FA stock held by Individual B by reason of owning the DT stock, determined under § 1.7874–2(f)(2), over 100 shares of FA stock outstanding after the DT acquisition).

* * * * *

(i) *Expiration date.* The applicability of this section expires on or before April 4, 2019.

■ **Par. 13.** Section 1.7874–8T is amended by revising the third sentence of paragraph (h) *Example 1.*(ii), the fifth sentence of paragraph (h) *Example 2.*(ii), the ninth sentence of paragraph (h) *Example 3.*(ii), and paragraph (j) to read as follows:

§ 1.7874–8T Disregard of certain stock attributable to multiple domestic entity acquisitions (temporary).

* * * * *

(h) * * *

Example 1. * * *

(ii) * * * As a result, and because there were no redemptions of FA stock, the excluded amount is $150x (calculated as 100, the total number of prior acquisition shares, multiplied by $1.50x, the fair market value of a single share of FA stock on the completion date with respect to the DT2 acquisition). * * *

* * * * *

Example 2. * * *

(ii) * * * As a result, the excluded amount is $112.50x, calculated as 75 (100, the total number of prior acquisition shares, less 25, the allocable redeemed shares) multiplied by $1.50x (the fair market value of a single share of FA stock on the completion date with respect to the DT2 acquisition). * * *

* * * * *

Example 3. * * *

(ii) * * * Accordingly, the excluded amount is $112.50x, calculated as 150 (200, the total number of prior acquisition shares, less 50, the allocable redeemed shares) multiplied by $0.75x (the fair market value of a single class of FA stock on the completion date with respect to the DT2 acquisition). * * *

* * * * *

(j) *Expiration date.* The applicability of this section expires on or before April 4, 2019.

■ **Par. 14.** Section 1.7874–9T is amended by revising paragraph (e)(1), the first sentence of paragraph (f) *Example.*(ii)(A), the seventh sentence of paragraph (f) *Example.*(iv) and paragraph (h) to read as follows:

§ 1.7874–9T Disregard of certain stock in third-country transactions (temporary).

* * * * *

(e) * * *

(1) *Acquisition of multiple foreign corporations that are tax residents of the same foreign country.* When multiple foreign acquisitions occur pursuant to the same plan (or a series of related transactions) and two or more of the acquired foreign corporations were subject to tax as a resident of the same foreign country before the foreign acquisitions and all related transactions, then those foreign acquisitions are treated as a single foreign acquisition and those acquired foreign corporations are treated as a single acquired foreign corporation for purposes of this section.

* * * * *

(f) * * *

Example. * * *

(ii) * * *

(A) The FT acquisition is a foreign acquisition because, pursuant to the FT acquisition, FA (a foreign acquiring corporation) acquires 100 percent of the stock of FT and is thus treated as indirectly acquiring 100 percent of the properties held by FT (an acquired foreign corporation). * * *

* * * * *

(iv) * * * FA's indirect acquisition of FT's properties is a covered foreign acquisition because 35 shares of FA stock (the shares received by Individual B) are held by reason of holding stock in FT; thus, the foreign ownership percentage is 100 percent (35/35). * * *

* * * * *

(h) *Expiration date.* The applicability of this section expires on or before April 4, 2019.

■ **Par. 15.** Section 1.7874–10T is amended by revising paragraphs (d)(2) and (j) to read as follows:

§ 1.7874–10T Disregard of certain distributions (temporary).

* * * * *

(d) * * *

(2) On the completion date, former domestic entity shareholders or former domestic entity partners, as applicable, in the aggregate, own (applying the attribution rules of section 318(a) with the modifications described in section 304(c)(3)(B)) less than five percent (by vote and value) of the stock of (or a partnership interest in) each member of the expanded affiliated group.

* * * * *

(j) *Expiration date.* This section expires on or before April 4, 2019.

■ **Par. 16.** Section 1.7874–11T is amended by revising paragraphs (b)(1) and (2), and (g) to read as follows:

§ 1.7874–11T Rules regarding inversion gain (temporary).

* * * * *

(b) * * * (1) *General rule.* Except as provided in paragraphs (b)(2) and (3) of this section, inversion gain includes income (including an amount treated as a dividend under section 78) or gain recognized by an expatriated entity for any taxable year that includes any portion of the applicable period by reason of a direct or indirect transfer of stock or other properties or license of any property either as part of the domestic entity acquisition, or after such acquisition if the transfer or license is to a specified related person.

(2) *Exception for property described in section 1221(a)(1).* Inversion gain does not include income or gain recognized by reason of the transfer or license, after the domestic entity acquisition, of property that is described in section 1221(a)(1) in the hands of the transferor or licensor.

* * * * *

(g) *Expiration date.* This section expires on or before April 4, 2019.

■ **Par. 17.** Section 1.7874–12T is amended by revising paragraph (c) to read as follows:

§ 1.7874–12T Definitions (temporary).

* * * * *

(c) *Expiration date.* This section expires on or before April 4, 2019.

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2016–14649 Filed 6–22–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

30 CFR Part 250

[Docket ID: BSEE–2016–0006; EEEE500000 16XE1700DX EX1SF0000.DAQ000]

RIN 1014–AA15

Oil and Gas and Sulphur Operations in the Outer Continental Shelf—Technical Corrections; Correction

AGENCY: Bureau of Safety and Environmental Enforcement (BSEE), Interior.

ACTION: Final rule; correction.

SUMMARY: The Bureau of Safety and Environmental Enforcement (BSEE) is correcting a final rule that appeared in the **Federal Register** on June 6, 2016 (81 FR 36145).

DATES: Effective July 28, 2016.

FOR FURTHER INFORMATION CONTACT: Betty Cox, Regulations and Standards Branch at (703) 787–1665 or email at *regs@bsee.gov.*

SUPPLEMENTARY INFORMATION: In the FR Doc. 2016–12487 appearing on page 36150 in the **Federal Register** of Monday, June 6, 2016, the following correction is made:

§ 250.904 [Corrected]

1. On page 36150, in the first column, remove amendatory instruction 20 correcting § 250.904.

Dated: June 17, 2016.

Robert W. Middleton,

Deputy Chief, Office of Offshore Regulatory Programs.

[FR Doc. 2016–14850 Filed 6–22–16; 8:45 am]

BILLING CODE 4310–VH–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0474]

Drawbridge Operation Regulation; Willamette River, Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Morrison Bridge across the Willamette River, mile 12.8, at Portland, Oregon. The deviation is necessary to accommodate Multnomah County's replacement of the bridge decking. This deviation allows the bridge to only open half of the span, single leaf, to allow for the replacement of bridge decking. The deviation also allows the vertical clearance to be reduced due to the project's containment system.

DATES: This deviation is effective from 6 a.m. on April 1, 2017 until 7 p.m. on September 27, 2017.

ADDRESSES: The docket for this deviation, [USCG–2016–0474] is available at *http://www.regulations.gov.* Type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *d13-pf-d13bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION: Multnomah County has requested that the Morrison Bridge across the Willamette River, mile 12.8, be allowed to only open half the span, 92 feet, as opposed to a full opening, 185 feet, to accommodate the replacement of the bridge decking. The County has also requested to reduce the vertical clearance of the non-opening side of the span with scaffolding erected 10 feet below the lower bridge cord for a containment system and to require at least a two hour advance notice for an opening. The Morrison Bridge is a double bascule bridge. When the bascule span is in the closed-to-navigation position, the bridge provides 69 feet of vertical clearance, which will be reduced to 59 feet with the containment system in place. The normal operating schedule for the Morrison Bridge is in accordance with 33 CFR 117.897(c)(3)(iv). The vertical clearance is above Columbia River Datum 0.0.

The deviation period is from 6 a.m. on April 1, 2017 until 7 p.m. on September 27, 2017. The deviation allows the Morrison Bridge operator to only open half the span for maritime traffic with at least a two hour advanced notice. Waterway usage on this part of the Willamette River includes vessels ranging from commercial tug and barge to small pleasure craft.

Vessels able to pass through the Morrison Bridge in the closed position may do so at any time. A tug will be on site to assist vessels through the single leaf span opening upon request. The bridge will be able to open half the span for emergencies with a two hour notice and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridges so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: June 17, 2016.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2016–14846 Filed 6–22–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2016–0260]

Safety Zone; San Francisco Giants Fireworks, San Francisco Bay, San Francisco, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the San Francisco Giants Fireworks display in the Captain of the Port, San Francisco area of responsibility during the dates and times noted below. This action is necessary to protect life and property of the maritime public from the hazards associated with the fireworks display. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone, unless authorized by the Patrol Commander (PATCOM).

DATES: The regulations in 33 CFR 165.1191, Table 1, Item number 1 will be enforced from 11 a.m. on June 24, 2016 to 1 a.m. on June 25, 2016.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice of enforcement, call or email Lieutenant Junior Grade Christina Ramirez, U.S. Coast Guard Sector San Francisco; telephone (415) 399–3585 or email at *D11-PF-MarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone established in 33 CFR 165.1191, Table 1, Item number 1 on June 24, 2016. From 11 a.m. until 10 p.m. on June 24, 2016 the safety zone will be enforced in the navigable waters around and under the fireworks barge within a radius of 100 feet throughout the loading and transit of fireworks barge at the launch site and until the start of the fireworks display. As indicated below, during the fireworks display, the size of the safety zone will increase to accommodate fall-out and other debris during the display.

From 11 a.m. until 5 p.m. on June 24, 2016 the fireworks barge will be loading pyrotechnics at Pier 50 in San Francisco, CA. From 5 p.m. to 9:30 p.m. on June 24, 2016 the fireworks barge will remain at Pier 50. From 9:30 p.m. to 10 p.m. on June 24, 2016 the loaded fireworks barge will transit from Pier 50 to the launch site near Pier 48 in approximate position 37°46′36″ N., 122°22′56″ W. (NAD83). At the conclusion of the baseball game, approximately 10 p.m. on June 24, 2016, the safety zone will increase in size and encompass the navigable waters around and under the fireworks barge within a radius of 700 feet in approximate position 37°46′36″ N., 122°22′56″ W. (NAD83) for the San Francisco Giants Fireworks display in 33 CFR 165.1191, Table 1, Item number 1. Upon the conclusion of the fireworks display, the safety zone shall terminate.

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM. Additionally, each person who receives notice of a lawful order or direction issued by an official patrol vessel shall obey the order or direction. The PATCOM is empowered to forbid entry into and control the regulated area. The PATCOM shall be designated by the Commander, Coast Guard Sector San Francisco. The PATCOM may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

This notice of enforcement is issued under authority of 33 CFR 165.1191 and 5 U.S.C. 552(a). In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of the safety zone and its enforcement period via the Local Notice to Mariners.

If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice of enforcement, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: June 3, 2016.

Patrick S. Nelson,

Captain, U.S. Coast Guard, Captain of the Port San Francisco, Acting.

[FR Doc. 2016–14911 Filed 6–22–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–201 5–1123]

RIN 1625–AA00

Safety Zone; Pleasure Beach Bridge, Bridgeport, CT

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone within the Coast Guard Sector Long Island Sound (LIS) Captain of the Port (COTP) Zone. This temporary final rule is necessary to provide for the safety of life on navigable waters. Entry into, transit through, mooring, or anchoring within the safety zone is prohibited unless authorized by COTP Sector LIS.

DATES: This rule is effective without actual notice from 12:01 a.m. on June 23, 2016 until 12:01 a.m. on July 1, 2016. For the purposes of enforcement, actual notice will be used from January 1, 2016, until June 23, 2016.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2015–1123]. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, contact Lieutenant Junior Grade Martin Betts, Prevention Department, Coast Guard Sector Long Island Sound, telephone (203) 468–4432, email *Martin.B.Betts@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

COTP	Captain of the Port
OHS	Department of Homeland Security
E.O.	Executive order
FR	Federal Register
NPRM	Notice of Proposed Rulemaking
NAD 83	North American Datum 1983

II. Background Information and Regulatory History

This rulemaking establishes a safety zone for the waters around Pleasure Beach Bridge, Bridgeport, CT. Corresponding regulatory history is discussed below.

The Coast Guard was made aware on December 9, 2015, of damage sustained to Pleasure Beach Bridge, the result of which created a hazard to navigation. In response, on Tuesday, December 22, 2015, the Coast Guard published a temporary final rule (TFR) entitled, "Safety Zone; Pleasure Beach Bridge, Bridgeport CT" in the **Federal Register** (80 FR 79480). We received no comments on this rule. The rule expired on January 1, 2016.

The degraded condition of the Pleasure Beach Bridge structure presents a continued hazard to navigation in the waterway. The Coast Guard is establishing this temporary final rule to mitigate the risk posed by the bridge structure and to allow responsible parties ample time to develop plans to reduce or eliminate the hazard.

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM with respect to this rule because doing so would be impracticable and contrary to the public interest. There is insufficient time to publish an NPRM and solicit comments from the public before establishing a safety zone to address the existing hazard to navigation. The nature of the navigational hazard requires the immediate establishment of a safety zone. Publishing an NPRM and delaying the effective date of this rule to await public comment inhibits the Coast Guard's ability to fulfill its statutory mission to protect ports, waterways and the maritime public.

Under 5 U.S.C. 553(d)(3), and for the same reasons stated in the preceding paragraph, the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Legal Authority and Need for Rule

The legal basis for this temporary rule is 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5 and Department of Homeland Security Delegation No. 0170. 1 which collectively authorize the Coast Guard to define regulatory safety zones.

On December 9, 2015, the Coast Guard was made aware of damage sustained to Pleasure Beach Bridge, Bridgeport, CT that has created a hazard to navigation. After further analysis of the bridge structure, the Coast Guard concluded that the overall condition of the structure created a continued hazard to navigation. The COTP Sector LIS has determined that the safety zone established by this temporary final rule is necessary to provide for the safety of life on navigable waterways.

IV. Discussion of the Rule

The safety zone established by this rule will cover all navigable waters of the entrance channel to Johnsons Creek in the vicinity of Pleasure Beach Bridge, Bridgeport, CT. This safety zone will be bound inside an area that starts at a point on land at position 41–10.2N, 073–10.7W and then east along the shoreline to a point on land at position 41–9.57N, 073–9.54W and then south across the channel to a point on land at position 41–9.52N, 073–9.58W and then west along the shoreline to a point on land at position 41–9.52N, 073–10.5W and then north across the channel back to the point of origin.

This rule prevents vessels from entering, transiting, mooring, or anchoring within the area specifically designated as a safety zone during the period of enforcement unless authorized by the COTP or designated representative.

The Coast Guard will notify the public and local mariners of this safety zone through appropriate means, which may include, but are not limited to, publication in the **Federal Register**, the Local Notice to Mariners, and Broadcast Notice to Mariners.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and E.O.s related to rulemaking.

Below we summarize our analyses based on these statutes and E.O.s and we discuss First Amendment rights of protesters.

A. Regulatory Planning and Review

E.O.s 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under E.O. 12866. Accordingly, it has not been reviewed by the Office of Management and Budget. The Coast Guard determined that this rulemaking is not a significant regulatory action for the following reasons: (1) The enforcement of this safety zone will be relatively short in duration; (2) persons or vessels desiring to enter the safety zone may do so with permission from the COTP Sector LIS or a designated representative; (3) this safety zone is designed in a way to limit impacts on vessel traffic, permitting vessels to navigate in other portions of the waterway not designated as a safety zone; and (4) the Coast Guard will notify the public of the enforcement of this rule via appropriate means, such as via Local Notice to Mariners and Broadcast Notice to Mariners to increase public awareness of this safety zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This temporary final rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to enter, transit, anchor, or moor within a safety zone during the period of enforcement, from January 1, 2016 to July 1, 2016. However, this temporary final rule will not have a significant economic impact on a substantial number of small entities for the same reasons discussed in the Regulatory Planning and Review section.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under E.O. 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

Also, this rule does not have tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M 16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This temporary rule involves the establishment of a safety zone. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination, and EA Checklist, WILL BE in the docket for review. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T01–1123 to read as follows:

§ 165.T01–1123 Safety Zone; Pleasure Beach Bridge, Bridgeport, CT.

(a) *Location.* The following area is a safety zone: All navigable waters of the entrance channel to Johnsons Creek in the vicinity of Pleasure Beach Bridge, Bridgeport, CT bound inside an area that starts at a point on land at position 41–10.2N, 073–10.7W and then east along the shoreline to a point on land at position 41–9.57N, 073–9.54W and then south across the channel to a point on land at position 41–9.52N, 073–9.58W and then west along the shoreline to a point on land at position 41–9.52N, 073–10.5W and then north across the channel back to the point of origin.

(b) *Enforcement period.* This rule will be enforced from 12:01 a.m. on January 1, 2016 to 12:01 a.m. on July 1, 2016.

(c) *Definitions.* The following definitions apply to this section: A "designated representative" is any Coast Guard commissioned, warrant or petty officer of the U.S. Coast Guard who has been designated by the COTP, Sector Long Island Sound, to act on his or her behalf. The designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via VHF–FM radio or loud hailer. "Official patrol vessels" may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP Sector Long Island Sound. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

(d) *Regulations.* (1) The general regulations contained in § 165.23 apply.

(2) In accordance with the general regulations in § 165.23, entry into or movement within this zone is prohibited unless authorized by the Captain of the Port, Long Island Sound.

(3) Operators of vessels desiring to enter or operate within the safety zone should contact the COTP Sector Long Island Sound at 203–468–4401 (Sector LIS command center) or the designated representative via VHF channel 16 to obtain permission to do so.

(4) Any vessel given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP Sector Long Island Sound, or the designated on-scene representative.

(5) Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light or other means, the operator of the vessel shall proceed as directed.

Dated: December 30, 2015.

E.J. Cubanski, III,

Captain, U.S. Coast Guard, Captain of the Port Sector Long Island Sound.

Editorial note: This document was received for publication by the Office of Federal Register on June 20, 2016.

[FR Doc. 2016–14908 Filed 6–22–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52 and 81

[EPA–R04–OAR–2016–0018; FRL–9948–02–Region 4]

Air Plan Approval and Air Quality Designation; TN; Redesignation of the Shelby County 2008 8-Hour Ozone Nonattainment Area to Attainment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On January 19, 2016, the State of Tennessee, through the Tennessee Department of Environment and Conservation (TDEC), Air Pollution Control Division, submitted a request for the Environmental Protection Agency (EPA) to redesignate the portion of Tennessee that is within the Memphis, Tennessee-Mississippi-Arkansas (Memphis, TN-MS-AR) 2008 8-hour ozone nonattainment area (hereafter referred to as the "Memphis, TN-MS-AR Area" or "Area") and a related State Implementation Plan (SIP) revision containing a maintenance plan and base year inventory for the Area. EPA is taking the following separate final actions related to the January 19, 2016, redesignation request and SIP revision: Approving the base year emissions inventory for the Area into the SIP; determining that the Memphis, TN-MS-AR Area is attaining the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS); approving the State's plan for maintaining attainment of the 2008 8-hour ozone NAAQS in the Area, including the motor vehicle emissions budgets (MVEBs) for nitrogen oxides (NO_X) and volatile organic compounds (VOCs) for the year 2027 for the Tennessee portion of the Area, into the SIP; and redesignating the Tennessee portion of the Area to attainment for the 2008 8-hour ozone NAAQS. Additionally, EPA finds the MVEBs for the Tennessee portion of the Area adequate for the purposes of transportation conformity.

DATES: This rule will be effective July 25, 2016.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2016–0018. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jane Spann, Air Regulatory Management Section, Air Planning and Implementation Branch, Pesticides and Toxics Management Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Ms. Spann can be reached by phone at (404) 562–9029 or via electronic mail at *spann.jane@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On May 21, 2012, EPA designated areas as unclassifiable/attainment or nonattainment for the 2008 8-hour ozone NAAQS that was promulgated on March 27, 2008. *See* 77 FR 30088. The Memphis, TN-MS-AR Area was designated nonattainment for the 2008

8-hour ozone NAAQS on May 21, 2012 (effective July 20, 2012) using 2008–2010 ambient air quality data. *See* 77 FR 30088. The Memphis, TN-MS-AR Area consists of a portion of DeSoto County in Mississippi, all of Shelby County in Tennessee, and all of Crittenden County in Arkansas. At the time of designation, the Memphis, TN-MS-AR Area was classified as a marginal nonattainment area for the 2008 8-hour ozone NAAQS. In the final implementation rule for the 2008 8-hour ozone NAAQS (SIP Implementation Rule),[1] EPA established ozone nonattainment area attainment dates based on Table 1 of section 181(a) of the Clean Air Act (CAA or Act). This established an attainment date three years after the July 20, 2012, effective date for areas classified as marginal areas for the 2008 8-hour ozone nonattainment designations. Therefore, the Memphis, TN-MS-AR Area's attainment date is July 20, 2015.

Based on the 2008 8-hour ozone nonattainment designation for the Memphis, TN-MS-AR Area, Tennessee was required to develop a nonattainment SIP revision addressing certain Clean Air Act (CAA or Act) requirements. Specifically, pursuant to CAA section 182(a)(3)(B) and section 182(a)(1), the state was required to submit a SIP revision addressing emissions statements and base year emissions inventory requirements, respectively, for its portion of the Area. EPA approved the emissions statements requirements for the Tennessee portion of the Area into the SIP in a final action published on March 5, 2015. *See* 80 FR 11974.

On January 19, 2016, TDEC requested that EPA redesignate Tennessee's portion of the Memphis, TN-MS-AR Area to attainment for the 2008 8-hour ozone NAAQS, and submitted a SIP revision containing a section 182(a)(1) base year emissions inventory and the State's plan for maintaining attainment of the 2008 8-hour ozone standard in the Area, including the MVEBs for NO_X and VOC for the year 2027 for the Tennessee portion of the Area.[2] In a notice of proposed rulemaking (NPRM) published on April 19, 2016, EPA proposed to: (1) Approve and incorporate the base year emissions inventory into the SIP as meeting the requirements of section 182(a)(1); (2) determine that the Memphis, TN-MS-AR Area is attaining the 2008 8-hour ozone NAAQS; (3) approve and incorporate into the Tennessee SIP the State's plan for maintaining attainment of the 2008 8-hour ozone standard in the Area, including the 2027 MVEBs for NO_X and VOC for Tennessee's portion of Memphis, TN-MS-AR Area; and (4) redesignate the Tennessee portion of the Area to attainment for the 2008 8-hour ozone NAAQS. *See* 81 FR 22948. In that notice, EPA also notified the public of the status of the Agency's adequacy determination for the NO_X and VOC MVEBs for Tennessee's portion of Memphis, TN-MS-AR Area. No comments were received on the April 19, 2016, proposed rulemaking. The details of Tennessee's submittal and the rationale for EPA's actions are further explained in the NPRM. *See* 81 FR 22948 (April 19, 2016).

II. What are the effects of these actions?

Approval of Tennessee's redesignation request changes the legal designation of Shelby County in the Memphis, TN-MS-AR Area, found at 40 CFR 81.325, from nonattainment to attainment for the 2008 8-hour ozone NAAQS. Approval of Tennessee's associated SIP revision also incorporates a section 182(a)(1) base year emissions inventory and a plan into the SIP for maintaining the 2008 8-hour ozone NAAQS in the Tennessee portion of the Area through 2027. The maintenance plan establishes NO_X and VOC MVEBs for 2027 for the Shelby County, Tennessee and includes contingency measures to remedy any future violations of the 2008 8-hour ozone NAAQS and procedures for evaluating potential violations. The MVEBs for the Tennessee portion of the Memphis, TN-MS-AR Area, along with the allocations from the safety margin, are provided in the table below.[3]

MVEBs FOR THE TENNESSEE PORTION OF THE MEMPHIS, TN-MS-AR AREA

[tpd]

	2027	
	NO_X	VOC
On-Road Emissions	12.51	5.81
Safety Margin Allocated to MVEBs	49.04	13.19
Conformity MVEBs	61.56	19.01

III. Final Action

EPA is taking a number of final actions regarding Tennessee's January 19, 2016, request to redesignate the Tennessee portion of the Memphis, TN-MS-AR Area to attainment and associated SIP revision. First, EPA is approving and incorporating Tennessee's section 182(a)(1) base year emissions inventory for the Tennessee portion of the Area into the SIP.

Second, EPA is determining that the Memphis, TN-MS-AR Area is attaining the 2008 8-hour ozone NAAQS.

Third, EPA is approving and incorporating the maintenance plan for the Tennessee portion of the Memphis, TN-MS-AR Area, including the NO_X and VOC MVEBs for 2027, into the Tennessee SIP. The maintenance plan demonstrates that the Area will continue to maintain the 2008 8-hour ozone NAAQS through 2027.

Fourth, EPA is determining that Tennessee has met the criteria under CAA section 107(d)(3)(E) for redesignation of the State's portion of the Memphis, TN-MS-AR Area from nonattainment to attainment for the 2008 8-hour ozone NAAQS. On this basis, EPA is approving Tennessee's redesignation request. As mentioned above, approval of the redesignation request changes the official designation of Shelby County, Tennessee for the 2008 8-hour ozone NAAQS from nonattainment to attainment, as found at 40 CFR part 81.

EPA is also notifying the public that EPA finds the newly-established NO_X and VOC MVEBs for the Tennessee portion of the Memphis, TN-MS-AR Area adequate for the purpose of transportation conformity. Within 24 months from this final rule, the transportation partners will need to demonstrate conformity to the new NO_X and VOC MVEBs pursuant to 40 CFR 93.104(e)(3).

IV. Statutory and Executive Order Reviews

Under the CAA, redesignation of an area to attainment and the accompanying approval of a maintenance plan under section

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[1] This rule, entitled Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements and published at 80 FR 12264 (March 6, 2015), addresses a range of nonattainment area SIP requirements for the 2008 ozone NAAQS, including requirements pertaining to attainment demonstrations, reasonable further progress (RFP), reasonably available control technology (RACT), reasonably available control measures (RACM), major new source review (NSR), emission inventories, and the timing of SIP submissions and of compliance with emission control measures in the SIP. This rule also addresses the revocation of the 1997 ozone NAAQS and the anti-backsliding requirements that apply when the 1997 ozone NAAQS are revoked.

[2] The Tennessee Department of Environment and Conservation Air Pollution Control Board adopted the SIP revision containing the maintenance plan on January 13, 2016.

[3] As discussed in the NPRM, the safety margin is the difference between the attainment level of emissions (from all sources) and the projected level of emissions (from all sources) in the maintenance plan. Tennessee chose to allocate a portion of the available safety margin to the NO_X and VOC MVEBs for 2027. TDEC has allocated 49.04 tpd of the NO_X safety margin to the 2027 NO_X MVEB and 13.19 tpd of the VOC safety margin to the 2027 VOC MVEB.

107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those imposed by state law. A redesignation to attainment does not in and of itself create any new requirements, but rather results in the applicability of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, these actions merely approve state law as meeting federal requirements and do not impose additional requirements beyond those imposed by state law. For this reason, these actions:

- Are not significant regulatory actions subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- are certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- do not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- are not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- will not have disproportionate human health or environmental effects under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. These actions are not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of these actions must be filed in the United States Court of Appeals for the appropriate circuit by August 22, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of these actions for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. These actions may not be challenged later in proceedings to enforce their requirements. *See* section 307(b)(2).

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

40 CFR Part 81

Environmental protection, Air pollution control.

Dated: June 10, 2016.

Heather McTeer Toney,

Regional Administrator, Region 4.

40 CFR parts 52 and 81 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart RR—Tennessee

■ 2. Section 52.2220(e) is amended by adding entries for "2008 8-hour Ozone Maintenance Plan for the Memphis TN-MS-AR Area" and "2008 8-hour Ozone Emissions Inventory for the Memphis TN-MS-AR Area" at the end of the table to read as follows:

§ 52.2220 Identification of plan.

* * * * *

(e) * * *

EPA APPROVED TENNESSEE NON-REGULATORY PROVISIONS

Name of non-regulatory SIP provision	Applicable geographic or nonattainment area	State effective date	EPA approval date	Explanation
* * *	*	*	*	*
2008 8-hour Ozone Maintenance Plan for the Memphis TN-MS-AR Area.	Shelby County	01/13/2016	6/23/2016 [Insert citation of publication].	
2008 8-hour Ozone Emissions Inventory for the Memphis TN-MS-AR Area.	Shelby County	01/13/2016	6/23/2016 [Insert citation of publication].	

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 3. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

■ 4. In § 81.343, the table entitled "Tennessee—2008 8-Hour Ozone NAAQS (Primary and secondary)" is amended under "Memphis, TN-MS-AR:" by revising the entry for "Shelby County" to read as follows:

§ 81.343 Tennessee.

* * * * *

TENNESSEE—2008 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
* * * *	*		*	*
Memphis, TN-MS-AR: [2]				
Shelby County	6/23/2016	Attainment.		
* * * *	*		*	*

[1] This date is July 20, 2012, unless otherwise noted.

[2] Excludes Indian country located in each area, unless otherwise noted.

* * * * *

[FR Doc. 2016–14807 Filed 6–22–16; 8:45 am]

BILLING CODE 6560–50–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

45 CFR Parts 1230 and 2554

RIN 3045–AA65

Civil Monetary Penalties Inflation Adjustment

AGENCY: Corporation for National and Community Service.

ACTION: Interim final rule.

SUMMARY: The Corporation for National and Community Service (CNCS) is updating its regulations to reflect required inflation-related increases to the civil monetary penalties in its regulations, pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

DATES: *Effective date:* This rule is effective August 1, 2016.

Comment due date: Technical comments may be submitted until July 25, 2016.

ADDRESSES: You may send your comments electronically through the Federal government's one-stop rulemaking Web site at *www.regulations.gov*. Also, you may mail or deliver your comments to Phyllis Green, Executive Assistant, Office of General Counsel, at the Corporation for National and Community Service, 250 E Street SW., Washington, DC 20525. Due to continued delays in CNCS's receipt of mail, we strongly encourage comments to be submitted online electronically. The TDD/TTY number is 800–833–3722. You may request this notice in an alternative format for the visually impaired.

FOR FURTHER INFORMATION CONTACT: Phyllis Green, Executive Assistant, Office of General Counsel, at 202–606–6709 or email to *pgreen@cns.gov*. Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

The Corporation for National and Community Service (CNCS) is a federal agency that engages more than five million Americans in service through its AmeriCorps, Senior Corps, Social Innovation Fund, and Volunteer Generation Fund programs, and leads the President's national call to service initiative, United We Serve. For more information, visit *NationalService.gov*.

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114–74) (the "Act") to improve the effectiveness of civil monetary penalties and to maintain the deterrent effect of such penalties. The Act requires agencies to make a "catch-up" adjustment to the level of civil monetary penalties through an interim final rulemaking and to adjust the civil monetary penalties for inflation annually.

II. Method of Calculation

CNCS identified two civil monetary penalties in its regulations and calculated the catch-up adjustments as specified in the February 24, 2016, OMB Memorandum of the Heads of Executive Departments and Agencies, M–16–06, *Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015*. A civil monetary penalty under the act is a penalty, fine, or other sanction that is for a specific monetary amount as provided by Federal law or has a maximum amount provided for by federal law and is assessed or enforced by an agency pursuant to Federal law and is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts. (*See* 28 U.S.C. 2461 note).

The inflation adjustment for each applicable civil monetary penalty is determined using the percent increase in the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October of the year in which the amount of each civil money penalty was most recently established or modified.

CNCS identified two civil penalties in its regulations: (1) The penalty associated with Restrictions on Lobbying (45 CFR 1230.400) and (2) the penalty associated with the Program Fraud Civil Remedies Act (45 CFR 2554.1).

In 1989, Congress established civil monetary penalties related to Restrictions on Lobbying (Section 319, Pub. L. 101–121; 31 U.S.C. 1352) ranging from $10,000 to $100,000. The multiplier for 1989 is 1.89361. Thus, the new range of possible civil monetary penalties is from $18,936 to $189,361.

The Program Fraud Civil Remedies Act of 1986 (Pub. L. 99–509) established a civil monetary penalty with an upper limit of $5,000. The multiplier for 1986 is 2.15628. Thus, the new upper limit of the civil monetary penalty is $10,781.

III. Summary of Final Rule

This final rule adjusts the civil monetary penalty amounts related to Restrictions on Lobbying (45 CFR 1230.400) and the Program Fraud Civil Remedies Act of 1986 (45 CFR 2554.1). The range of civil monetary penalties related to Restrictions on Lobbying increase from $10,000 to $100,000 to $18,936 to $189,361. The civil monetary penalties for the Program Fraud Civil Remedies Act of 1986 increase from up to $5,000 to up to $10,781.

IV. Regulatory Procedures

A. Determination of Good Cause for Publication Without Notice and Comment

CNCS finds, under 5 U.S.C. 553(b)(3)(B), that there is good cause to except this rule from the public notice and comment provisions of the Administrative Procedure Act, 5 U.S.C. 553(b). Because CNCS is implementing a final rule pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which requires CNCS to update its regulations based on a prescribed formula, CNCS has no discretion in the nature or amount of the change to the civil monetary penalties. Therefore, notice and comment for these proscribed updates is impracticable and unnecessary. As an interim final rule, no further regulatory action is required for the issuance of this legally binding rule. If you would like to provide technical comments, however, they may be submitted until July 25, 2016.

B. Review Under Procedural Statutes and Executive Orders

CNCS has determined that making technical changes to the amount of civil monetary penalties in its regulations does not trigger any requirements under procedural statutes and Executive Orders that govern rulemaking procedures.

V. Effective Date

This rule is effective August 1, 2016. The adjusted civil penalty amounts apply to civil penalties assessed after August 1, 2016 when the violation occurred after November 2, 2015. If the violation occurred prior to November 2, 2015 or a penalty was assessed prior to August 1, 2016, the pre-adjustment civil penalty amounts in effect prior to August 1, 2106 will apply.

List of Subjects

45 CFR Part 1230

Government contracts, Grant programs, Loan programs, Lobbying, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 2554

Claims, Fraud, Organization and functions (Government agencies), Penalties.

For the reasons discussed in the preamble, under the authority of 42 U.S.C. 12651c(c), the Corporation for National and Community Service amends chapters XII and XXV, title 45 of the Code of Federal Regulations as follows:

PART 1230—NEW RESTRICTIONS ON LOBBYING

■ 1. The authority citation for part 12301 continues to read as follows:

Authority: Section 319, Pub. L. 101–121 (31 U.S.C. 1352); Pub. L. 93–113; 42 U.S.C. 4951, *et seq.;* 42 U.S.C. 5060

§ 1230.400 [Amended]

■ 2. Amend § 1230.400 by:

■ a. In paragraphs (a), (b), and (e), removing "$10,000" and adding, in its place, "$18,936" each place it appears.

■ b. In paragraphs (a), (b), and (e), removing "$100,000" and adding, in its place, "$189,361" each place it appears.

Appendix A to Part 1230 [Amended]

■ 3. Amend appendix A to part 1230 by:

■ a. Removing "$10,000" and adding, in its place, "$18,936" each place it appears.

■ b. Removing "$100,000" and adding, in its place, "$189,361" each place it appears.

PART 2554—PROGRAM FRAUD CIVIL REMEDIES ACT REGULATIONS

■ 4. The authority citation for part 2554 continues to read as follows:

Authority: Pub. L. 99–509, Secs. 6101–6104, 100 Stat. 1874 (31 U.S.C. 3801–3812); 42 U.S.C. 12651c–12651d.

§ 2554.1 [Amended]

■ 5. Amend § 2554.1 by removing "$5,000" in paragraph (b) and adding, in its place, "$10,781".

Dated: June 16, 2016.

Jeremy Joseph,

General Counsel.

[FR Doc. 2016–14675 Filed 6–22–16; 8:45 am]

BILLING CODE 6050–28–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[FCC 16–70]

Service by Email for Notice of Petitions for Review and Appeals

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Federal Communications Commission (Commission) amends its rules to allow and in certain circumstances to require parties to give the Commission notice of lawsuits by email. First, it requires persons petitioning for judicial review who wish to participate in a "judicial lottery" to notify the Commission of the petition by email. This method will allow timely service, and will eliminate security concerns that arise through in-person service. Further, the new rule encourages, but does not require, notice by email for persons who petition for review but do not seek to participate in a lottery. It likewise encourages, but does not require, notice by email for persons who judicially appeal Commission decisions.

DATES: Effective July 25, 2016.

FOR FURTHER INFORMATION CONTACT: Richard Welch, 202–418–7225.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Order,* FCC 16–70, adopted on June 1, 2016, and released on June 3, 2016. The full text of this document will be available for public inspection and copying via ECFS, and during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554.

Synopsis

1. By this order, we revise Section 1.13 of our rules to allow and in certain circumstances require parties to give the Commission notice of lawsuits by email. First, we revise 47 CFR 1.13(a)(1) of our rules to change the procedure by which a party petitioning for review of a Commission decision under 47 U.S.C. 402(a) must notify the Commission in order to take advantage of the random selection procedures described in 28 U.S.C. 2112. That statute provides for a lottery to select a court when parties have petitioned for review of the same FCC decision in more than one court, provided that petitioners serve a copy of the petitions for review on the agency within ten days of issuance of the order under review. 28 U.S.C. 2112(a)(1), (3). Because the procedure is time sensitive

due to this ten-day statutory deadline, the Commission has established rules to ensure that its Office of General Counsel receives timely notice of the petition for review. 47 CFR 1.13(a)(1); *see Addition of New Section 1.13 to the Commission's Rules of Practice & Procedure,* 4 FCC Rcd 2092 (1989).

2. Until now, those rules have directed petitioners to make that service in person at the Office of General Counsel in the Commission's Washington, DC headquarters. However, that method of service is not easily reconciled with the security protocols that currently apply to other filings with the Commission. We therefore now revise our rules for these situations to require service by email according to specific procedures, as set out in the new rule. These procedures will allow for timely service on the Commission without raising the issues with respect to Commission security requirements that are currently presented by service in person. We also expect that this method of service will be more convenient for most petitioners and their counsel, especially those located outside of the Washington, DC metropolitan area. For parties who are not represented by counsel and who are unable to use email to effect service, we have retained a method to serve notice in person on the Office of General Counsel. Such parties must telephone prior to service to make arrangements, and are advised to do so at least a day before service, keeping in mind the ten-day statutory deadline by which service must be complete.

3. For the convenience of parties and the Commission, we also revise our rules to authorize—but not require—email notice of lawsuits against the Commission under 47 U.S.C. 402(b). Specifically, we revise section 1.13(b) of our rules, which applies to parties appealing certain licensing-related FCC actions under 47 U.S.C. 402(b), to authorize and encourage service of notices of appeal on the General Counsel by email. *See* 47 U.S.C. 402(c) (requiring notice on Commission); *cf.* Fed. R. App. P. 25(c)(1)(D) (permitting electronic service with consent of party). Because notices of appeal under section 402(b) are not as time-sensitive as lottery proceedings under 28 U.S.C. 2112, however, we do not require service by email, and parties may use non-electronic means of service, such as U.S. mail, as permitted by the Federal Rules of Appellate Procedure and any applicable local rules.

4. Finally, we amend the note to section 1.13 to also encourage service by email of petitions for review under 47 U.S.C. 402(a) by petitioners that are not seeking to participate in a judicial lottery pursuant to 28 U.S.C. 2112. Although there is no requirement under the Federal Rules of Appellate Procedure or section 402 for parties to serve the Commission with such petitions for review, service by email will assist the Commission in timely responding to litigation. Where service by email is impracticable for such petitioners, the Commission requests service by non-electronic means.

5. Because this is a revision to a procedural rule, notice and comment is not required in advance of its adoption. *See* 5 U.S.C. 553(b). For the same reason, we are also not required to perform a regulatory flexibility analysis, *see* 5 U.S.C. 603(a), or to submit the rule for review under the Congressional Review Act, *see* 5 U.S.C. 804(3)(C). Authority for this rulemaking is contained in 47 U.S.C. 154(i) and 154(j) and 28 U.S.C. 2112(a)(2).

List of Subjects in 47 CFR Part 1

Administrative practice and procedure, Lawyers, Litigation, and Telecommunications.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 1 as follows:

PART 1—PRACTICE AND PROCEDURE

■ 1. The authority citation for part 1 is revised to read as follows:

Authority: 47 U.S.C. 151, 154(i), 154(j), 155, 157, 160, 201, 225, 227, 303, 309, 332, 1403, 1404, 1451, 1452, and 1455.

■ 2. Section 1.13 is revised to read as follows:

§ 1.13 Filing of petitions for review and notices of appeals of Commission orders.

(a) *Petitions for review involving a judicial lottery pursuant to 28 U.S.C. 2112(a).* (1) This paragraph pertains to each party filing a petition for review in any United States court of appeals of a Commission Order pursuant to 47 U.S.C. 402(a) and 28 U.S.C. 2342(1), that wishes to avail itself of procedures established for selection of a court in the case of multiple petitions for review of the same Commission action, pursuant to 28 U.S.C. 2112(a). Each such party shall, within ten days after the issuance of that order, serve on the Office of General Counsel, by email to the address *LitigationNotice@fcc.gov,* a copy of its petition for review as filed and date-stamped by the court of appeals within which it was filed. Such copies of petitions for review must be received by the Office of General Counsel by 5:30 p.m. Eastern Time on the tenth day of the filing period. A return email from the Office of General Counsel acknowledging receipt of the petition for review will constitute proof of filing. Upon receipt of any copies of petitions for review according to these procedures, the Commission shall follow the procedures established in section 28 U.S.C. 2112(a) to determine the court in which to file the record in that case.

(2) If a party wishes to avail itself of procedures established for selection of a court in the case of multiple petitions for review of the same Commission action, pursuant to 28 U.S.C. 2112(a), but is unable to use email to effect service as described in paragraph (a)(1) of this section, it shall instead, within ten days after the issuance of the order on appeal, serve a copy of its petition for review in person on the General Counsel in the Office of General Counsel, 445 12th Street, SW., Washington, DC 20554. Only parties not represented by counsel may use this method. Such parties must telephone the Litigation Division of the Office of General Counsel beforehand to make arrangements at 202–418–1740. Parties are advised to call at least one day before service must be effected.

(3) Computation of time of the ten-day period for filing copies of petitions for review of a Commission order shall be governed by Rule 26 of the Federal Rules of Appellate Procedure. The date of issuance of a Commission order for purposes of filing copies of petitions for review shall be the date of public notice as defined in § 1.4(b) of the Commission's Rules, 47 CFR 1.4(b).

(b) *Notices of appeal pursuant to 47 U.S.C. 402(b).* Copies of notices of appeals filed pursuant to 47 U.S.C. 402(b) shall be served upon the General Counsel. The FCC consents to—and encourages—service of such notices by email to the address *LitigationNotice@fcc.gov.*

Note: For administrative efficiency, the Commission requests that any petitioner seeking judicial review of Commission actions pursuant to 47 U.S.C. 402(a) serve a copy of its petition on the General Counsel regardless of whether it wishes to avail itself of the procedures for multiple appeals set forth in 47 U.S.C. 2112(a). Parties are encouraged to serve such notice by email to the address *LitigationNotice@fcc.gov.*

[FR Doc. 2016–14096 Filed 6–22–16; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 81, No. 121
Thursday, June 23, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–7271; Directorate Identifier 2015–NM–099–AD]

RIN 2120–AA64

Airworthiness Directives; Fokker Services B.V. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Fokker Services B.V. Model F.28 Mark 0070 and 0100 airplanes. This proposed AD was prompted by heavy corrosion found on the wing rear spar lower girder. This proposed AD would require inspections of the affected areas, modification of the wing trailing edge lower skin panels, and corrective actions if necessary. We are proposing this AD to detect and correct corrosion of the wing rear spar lower girder. This condition could reduce the load-carrying capability of the wing, possibly resulting in structural failure and loss of the airplane.

DATES: We must receive comments on this proposed AD by August 8, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Fokker Services B.V., Technical Services Dept., P.O. Box 1357, 2130 EL Hoofddorp, the Netherlands; telephone +31 (0)88–6280–350; fax +31 (0)88–6280–111; email *technicalservices@fokker.com;* Internet *http://www.myfokkerfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–7271; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM 116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1137; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–7271; Directorate Identifier 2015–NM–099–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2015–0113, dated June 22, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for all Fokker Services B.V. Model F.28 Mark 0070, and 0100 airplanes. The MCAI states:

> On an F28 Mark 0070 aeroplane, heavy corrosion was found on the wing rear spar lower girder. At small spots the effective thickness of the vertical flange of the lower girder was almost lost. Subsequently, a number of inspections were accomplished on other aeroplanes to provide additional information on possible corrosion in this area. Because the rear spar lower girder between Wing Stations (WSTA) 9270 and 11794 is hidden from view by the inboard and outboard aileron balancing plates, it is possible that corrosion in this area remains undetected during the zonal inspections in zone 536 and 636 (MRB tasks 062505–00–01 and 062605–00–01).The heavy corrosion was not only found in the area between WSTA 9270 and 11794, but also in the area where the rear spar lower girder is directly visible.
>
> This condition, if not detected and corrected, reduces the load carrying capability of the wing, possibly resulting in structural failure and loss of the aeroplane.
>
> To address this potential unsafe condition, Fokker Services issued Service Bulletin (SB) SBF100–57–049 to provide instructions to detect and remove corrosion and to modify the wing trailing edge lower skin panels into access panels. SBF100–57–050 was issued to provide repair instructions.
>
> For the reasons described above, this [EASA] AD requires inspections of the affected areas and, depending on findings, accomplishment of applicable corrective action(s). This [EASA] AD also requires modification of the wing trailing edge lower skin panels into access panels [This modification is to provide ease of access for later inspection and repairs in the affected areas.], and reporting of the results of the inspections to Fokker Services.
>
> More information on this subject can be found in Fokker Services All Operators Message AOF100.197.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–7271.

Related Service Information Under 1 CFR Part 51

We reviewed Fokker Service Bulletin SBF100–57–049, dated March 24, 2015, which describes procedures for an inspection for corrosion of certain wing rear spar lower girder areas, modification of the wing trailing edge lower skin panels, and corrective actions if necessary. We also reviewed Fokker Service Bulletin SBF100–57–050, Revision 1, dated May 19, 2015, which describes procedures for repair of the wing spar. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

We estimate that this proposed AD affects 8 airplanes of U.S. registry.

We also estimate that it would take about 35 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $1,680 per product. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $37,240, or $4,655 per product.

In addition, we estimate that any necessary follow-on actions would take about 372 work-hours and require parts costing $7,600, for a cost of $39,220 per product. We have no way of determining the number of aircraft that might need this action.

We also estimate that it would take about 1 work-hour per product for reporting. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this reporting on U.S. operators to be $680, or $85 per product.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this proposed AD is 2120–0056. The paperwork cost associated with this proposed AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this proposed AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave. SW., Washington, DC 20591, ATTN: Information Collection Clearance Officer, AES–200.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Fokker Services B.V.: Docket No. FAA–2016–7271; Directorate Identifier 2015–NM–099–AD.

(a) Comments Due Date

We must receive comments by August 8, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Fokker Services B.V. Model F.28 Mark 0070 and 0100 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Reason

This AD was prompted by heavy corrosion found on the wing rear spar lower girder. We are issuing this AD to detect and correct corrosion of the wing rear spar lower girder. This condition could reduce the load-carrying capability of the wing, possibly resulting in structural failure and loss of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspection of the Wing Rear Spar Lower Girder From Wing Station (WSTA) 9270 to 11794

Within 1,000 flight cycles or 12 months, whichever occurs first after the effective date of this AD, accomplish a one-time detailed visual inspection for corrosion of the wing rear spar lower girder area from WSTA 9270 to 11794, in accordance with Part 1 of the Accomplishment Instructions of Fokker Service Bulletin SBF100–57–049, dated March 24, 2015.

(h) Modification of Wing Trailing Edge

Within 1,000 flight cycles or 12 months, whichever occurs first after the effective date of this AD, modify the wing trailing edge lower skin panels into access panels, in accordance with Part 1 of the Accomplishment Instructions of Fokker Service Bulletin SBF100–57–049, dated March 24, 2015.

(i) Inspection of the Wing Rear Spar Lower Girder From WSTA 2635 to 8700 and WSTA 11794 to 12975

Within 2,000 flight cycles or 24 months, whichever occurs first after the effective date of this AD, accomplish a one-time detailed visual inspection for corrosion of the wing rear spar lower girder area from WSTA 2635 to 8700 and WSTA 11794 to 12975, in accordance with Part 2 of the Accomplishment Instructions of Fokker Service Bulletin SBF100–57–049, dated March 24, 2015.

(j) Modification of Wing Rear Spar Lower Girder

(1) If during any inspection required by paragraph (g) or (i) of this AD, as applicable, corrosion is found, before further flight, remove the corrosion and determine the remaining thickness at the damaged spots, in accordance with the Accomplishment Instructions of Fokker Service Bulletin SBF100–57–049, dated March 24, 2015. If the remaining thickness at the damaged spots, as determined by this paragraph, is not within the tolerances specified in Fokker Service Bulletin SBF100–57–049, dated March 24, 2015, except as required by paragraph (k)(1) of this AD: Before further flight, accomplish the applicable corrective actions as defined in paragraph (j)(1)(i) or (j)(1)(ii) of this AD, as applicable.

(i) For corrosion damage found outboard of WSTA 8200 only: Repair in accordance with the Accomplishment Instructions of Fokker Service Bulletin SBF100–57–050, Revision 1, dated May 19, 2015.

(ii) Repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Fokker Services B.V.'s EASA Design Organization Approval (DOA).

(2) If during any inspection required by paragraph (g) or (i) of this AD, only damage to the surface protection is found, or if the remaining thickness at the damaged spots, as determined by paragraph (j)(1) of this AD, is within the tolerances specified in Fokker Service Bulletin SBF100–57–049, dated March 24, 2015, except as required by paragraph (k)(1) of this AD: Before further flight, restore the surface protection in accordance with the Accomplishment Instructions of Fokker Service Bulletin SBF100–57–049, dated March 24, 2015, except as required by paragraph (k)(2) of this AD.

(k) Exceptions to Service Information Specifications

(1) Where Fokker Service Bulletin SBF100–57–049, dated March 24, 2015, specifies the acceptability of smaller thickness or customized repairs: Before further flight, obtain acceptable tolerances, using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or EASA; or Fokker Services B.V.'s EASA DOA.

(2) Where Fokker Service Bulletin SBF100–57–049, dated March 24, 2015, specifies contacting Fokker for a customized repair: Before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or EASA; or Fokker Services B.V.'s EASA DOA.

(l) Reporting Requirements

Submit a report of the findings both positive and negative of the inspection required by paragraph (g) and (i) of this AD to Fokker Services, in accordance with the Accomplishment Instructions of Fokker Service Bulletin SBF100–57–049, dated March 24, 2015, at the time specified in paragraph (l)(1) or (l)(2) of this AD.

(1) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(2) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(m) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1137; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA; or Fokker Service B.V.'s EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Reporting Requirements:* A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(n) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2015–0113, dated June 22, 2015, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–7271.

(2) For service information identified in this AD, contact Fokker Services B.V., Technical Services Dept., P.O. Box 1357, 2130 EL Hoofddorp, the Netherlands; telephone +31 (0)88–6280–350; fax +31 (0)88–6280–111; email *technicalservices@fokker.com;* Internet *http://www.myfokkerfleet.com*. You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on June 14, 2016.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–14754 Filed 6–22–16; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2014–0213; FRL–9948–16–Region 7]

Approval and Promulgation of Implementation Plans; State of Iowa; Infrastructure SIP Requirements for the 1997 and 2006 Fine Particulate Matter ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS), and the Adoption of the 1997 $PM_{2.5}$ Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve elements of two State Implementation Plan (SIP) submissions from the State of Iowa for the Infrastructure SIP Requirements for the 1997 and 2006 Fine Particulate Matter ($PM_{2.5}$) National Ambient Air Quality Standards

(NAAQS). Infrastructure SIPs address the applicable requirements of Clean Air Act (CAA) section 110, which requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each new or revised NAAQS promulgated by the EPA. These SIPs are commonly referred to as "infrastructure" SIPs. The infrastructure requirements are designed to ensure that the structural components of each state's air quality management program are adequate to meet the state's responsibilities under the CAA. This action also proposes to approve the adoption of the 1997 $PM_{2.5}$ standard.

On September 8, 2011, EPA issued a Finding of Failure to Submit a Complete State Implementation Plan for several states, including Iowa. With respect to Iowa, the Finding of Failure to Submit covered the following 2006 $PM_{2.5}$ NAAQS infrastructure requirements: 110(a)(2)(A)–(C), (D)(i)(II) (prong 3 only), (E)–(H) and (J)–(M). This proposal to approve Iowa's infrastructure SIP for the 2006 $PM_{2.5}$ NAAQS addresses the September 8, 2011 finding.

DATES: Comments must be received on or before July 25, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2014–0213, to *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Heather Hamilton, Air Planning and Development Branch, U.S. Environmental Protection Agency, Region 7, 11201 Renner Boulevard, Lenexa, KS 66219; *telephone number:* (913) 551–7039; *email address: Hamilton.heather@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever "we," "us," or "our" is used, we refer to EPA. A detailed technical support document (TSD) is included in this rulemaking docket to address the following: A description of CAA section 110(a)(1) and (2) infrastructure SIPs; the applicable elements under sections 110(a)(1) and (2); EPA's approach to the review of infrastructure SIP submissions, and EPA's evaluation of how Iowa addressed the relevant elements of sections 110(a)(1) and (2). This section provides additional information by addressing the following questions:

I. What is being addressed in this document?
II. Have the requirements for approval of a SIP revision been met?
III. What action is EPA taking?

I. What is being addressed in this document?

The EPA is proposing to approve two submissions from the State of Iowa: The infrastructure SIP submissions for the 1997 and 2006 $PM_{2.5}$ NAAQS received on March 31, 2008 and July 29, 2013. The SIP submissions from Iowa address the requirements of CAA sections 110(a)(1) and (2) as applicable to the 1997 and 2006 $PM_{2.5}$ NAAQS. The March 31, 2008 SIP submission also included the state adoption of the 1997 $PM_{2.5}$ standard. The EPA is also proposing to approve this in today's action.

For the 1997 $PM_{2.5}$ NAAQS, the EPA took action to address section 110(a)(2)(D)(i)(I)—prongs 1 and 2 for Iowa. (72 FR 10380, March 8, 2007, as revised in 76 FR 48208, August 8, 2011). Therefore, in this proposal, we are not acting on these portions since they have already been acted upon by the EPA.

A TSD is included as part of the docket to discuss the details of this proposal.

II. Have the requirements for approval of a SIP revision been met?

The state submission has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submission also satisfied the completeness criteria of 40 CFR part 51, appendix V. In addition, as explained above and in more detail in the technical support document which is part of this document, the revision meets the substantive SIP requirements of the CAA, including section 110 and implementing regulations.

III. What action is EPA taking?

The EPA is proposing to approve two submissions from the State of Iowa: The infrastructure SIP submissions for the 1997 and 2006 $PM_{2.5}$ NAAQS received on March 31, 2008 and July 29, 2013. The SIP submissions from Iowa address the requirements of CAA sections 110(a)(1) and (2) as applicable to the 1997 and 2006 $PM_{2.5}$ NAAQS. This action also proposes to approve the adoption of the 1997 $PM_{2.5}$ standard.

The EPA's analysis of these submissions is addressed in a TSD as part of the docket to discuss the proposal.

Based upon review of the state's infrastructure SIP submissions and relevant statutory and regulatory authorities and provisions referenced in those submissions or referenced in Iowa's SIP, the EPA believes that Iowa's SIP will meet all applicable required elements of sections 110(a)(1) and (2) with respect to the 1997 and 2006 $PM_{2.5}$ NAAQS.

We are processing this as a proposed action because we are soliciting comments on this proposed action. Final rulemaking will occur after consideration of any comments.

Statutory and Executive Order Review

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Statutory Authority

The statutory authority for this action is provided by section 110 of the CAA, as amended (42 U.S.C. 7410).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Prevention of significant deterioration, Incorporation by reference, Intergovernmental relations, Particulate Matter, Reporting and recordkeeping requirements.

Dated: June 15, 2016.

Mark Hague,

Regional Administrator, Region 7.

For the reasons stated in the preamble, EPA proposes to amend 40 CFR part 52 as set forth below:

PART 52—Approval and Promulgation of Implementation Plans

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart Q—Iowa

■ 2. Section 52.820 is amended by adding entries (43) and (44) in numerical order to table (e) to read as follows:

§ 52.820 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED IOWA NONREGULATORY SIP PROVISIONS

Name of non-regulatory SIP revision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanation
* *	*	*	*	* * *
(43) Sections 110(a)(1) and (2) Infrastructure Requirements 1997 $PM_{2.5}$ NAAQS.	Statewide	3/21/08	6/23/16 [Insert **Federal Register** citation].	This action addresses the following CAA elements: 110(a)(2)(A), (B), (C), (D)(i)(II), prong 3, (E), (F), (G), (H), (J), (K), (L), and (M). 110(a)(2)(I) is not applicable.
(44) Sections 110(a)(1) and (2) Infrastructure Requirements 2006 $PM_{2.5}$ NAAQS.	Statewide	7/23/13	6/23/16 [Insert **Federal Register** citation].	This action addresses the following CAA elements: 110(a)(2)(A), (B), (C), (D)(i)(II), prong 3, (E), (F), (G), (H), (J), (K), (L), and (M). 110(a)(2)(I) is not applicable.

[FR Doc. 2016–14897 Filed 6–22–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2015–0824; FRL–9948–22–Region 5]

Air Plan Approval; Ohio; Infrastructure SIP Requirements for the 2012 $PM_{2.5}$ NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve elements of the state implementation plan (SIP) submission from Ohio regarding the infrastructure requirements of section 110 of the Clean Air Act (CAA) for the 2012 fine particulate matter ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS). The infrastructure requirements are designed to ensure that the structural components of each state's air quality management program are adequate to meet the state's responsibilities under the CAA.

DATES: Comments must be received on or before July 25, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2015–0824 at *http://www.regulations.gov* or via email to *aburano.douglas@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the Web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Joseph Ko, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–7947, *ko.joseph@epa.gov.*

SUPPLEMENTARY INFORMATION:

Throughout this document whenever "we," "us," or "our" is used, we mean EPA. This **SUPPLEMENTARY INFORMATION** section is arranged as follows:

I. What is the background of this SIP submission?
II. What guidance is EPA using to evaluate this SIP submission?
III. What is the result of EPA's review of this SIP submission?
IV. What action is EPA taking?
V. Statutory and Executive Order Reviews

I. What is the background of this SIP submission?

A. What state SIP submission does this rulemaking address?

This rulemaking addresses a submission from the Ohio Environmental Protection Agency (OEPA), describing its infrastructure SIP for the 2012 $PM_{2.5}$ NAAQS, dated December 4, 2015.

B. Why did the state make this SIP submission?

Under sections 110(a)(1) and (2) of the CAA, states are required to submit infrastructure SIPs to ensure that their SIPs provide for implementation, maintenance, and enforcement of the NAAQS, including the 2012 $PM_{2.5}$ NAAQS. These submissions must contain any revisions needed for meeting the applicable SIP requirements of section 110(a)(2), or certifications that their existing SIPs for the NAAQS already meet those requirements.

EPA highlighted this statutory requirement in an October 2, 2007, guidance document entitled "Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 1997 8-hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards" (2007 Memo) and has issued additional guidance documents, the most recent on September 13, 2013, "Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and (2)" (2013 Memo). The SIP submission referenced in this rulemaking pertains to the applicable requirements of section 110(a)(1) and (2), and addresses the 2012 $PM_{2.5}$ NAAQS. To the extent that the prevention of significant deterioration (PSD) program is non-NAAQS specific, a narrow evaluation of other NAAQS will be included in the appropriate sections.

C. What is the scope of this rulemaking?

EPA is acting upon the SIP submission from OEPA that addresses the infrastructure requirements of CAA sections 110(a)(1) and 110(a)(2) for the 2012 $PM_{2.5}$ NAAQS. The requirement for states to make a SIP submission of this type arises out of CAA section 110(a)(1). Pursuant to section 110(a)(1), states must make SIP submissions "within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof)," and these SIP submissions are to provide for the "implementation, maintenance, and enforcement" of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon EPA's taking any action other than promulgating a new or revised NAAQS. Section 110(a)(2) includes a list of specific elements that "[e]ach such plan" submission must address.

EPA has historically referred to these SIP submissions made for the purpose of satisfying the requirements of CAA sections 110(a)(1) and 110(a)(2) as "infrastructure SIP" submissions. Although the term "infrastructure SIP" does not appear in the CAA, EPA uses the term to distinguish this particular type of SIP submission from submissions that are intended to satisfy other SIP requirements under the CAA, such as "nonattainment SIP" or "attainment plan SIP" submissions to address the nonattainment planning requirements of part D of title I of the CAA, "regional haze SIP" submissions required by EPA rule to address the visibility protection requirements of CAA section 169A, and nonattainment new source review (NNSR) permit program submissions to address the permit requirements of CAA, title I, part D.

This rulemaking will not cover four substantive areas that are not integral to acting on a state's infrastructure SIP submission: (i) Existing provisions related to excess emissions during periods of start-up, shutdown, or malfunction at sources, that may be contrary to the CAA and EPA's policies addressing such excess emissions ("SSM"); (ii) existing provisions related to "director's variance" or "director's discretion" that purport to permit revisions to SIP-approved emissions limits with limited public process or without requiring further approval by EPA, that may be contrary to the CAA ("director's discretion"); (iii) existing provisions for PSD programs that may be inconsistent with current requirements of EPA's "Final New Source Review (NSR) Improvement Rule," 67 FR 80186 (December 31, 2002), as amended by 72 FR 32526 (June 13, 2007) ("NSR Reform"); and (iv) transport provisions under section 110(a)(2)(D). Instead, EPA has the authority to, and plans to, address each one of these substantive areas in separate rulemakings. A detailed history and interpretation of infrastructure SIP requirements can be found in EPA's May 13, 2014, proposed rule entitled, "Infrastructure SIP Requirements for the 2008 Lead NAAQS" in the section, "What is the scope of this rulemaking?" (*see* 79 FR 27241 at 27242–27245).

II. What guidance is EPA using to evaluate this SIP submission?

EPA's guidance for this infrastructure SIP submission is embodied in the 2007 Memo. Specifically, attachment A of the 2007 Memo (Required Section 110 SIP Elements) identifies the statutory elements that states need to submit in order to satisfy the requirements for an infrastructure SIP submission. EPA issued additional guidance documents, the most recent being the 2013 Memo, which further clarifies aspects of infrastructure SIPs that are not NAAQS specific.

III. What is the result of EPA's review of this SIP submission?

As noted in the 2013 Memo, pursuant to section 110(a), states must provide reasonable notice and opportunity for public hearing for all infrastructure SIP submissions. OEPA provided the opportunity for public comment for its 2012 $PM_{2.5}$ NAAQS infrastructure SIP submission during a public hearing held on November 23, 2015. The state did not receive any comments during the comment period. EPA is soliciting comment on our evaluation of the state's infrastructure SIP submission in this notice of proposed rulemaking. OEPA provided detailed synopses of how its SIP submission meets each of the requirements in section 110(a)(2) for the 2012 $PM_{2.5}$ NAAQS, as applicable. The following review evaluates the state's submission.

A. Section 110(a)(2)(A)—Emission Limits and Other Control Measures

This section requires SIPs to include enforceable emission limits and other control measures, means or techniques, schedules for compliance, and other related matters. EPA has long interpreted emission limits and control measures for attaining the standards as being due when nonattainment planning requirements are due.[1] In the context of an infrastructure SIP, EPA is not evaluating whether the existing SIP provisions satisfy nonattainment planning requirements. Instead, EPA is only evaluating whether the state's SIP has basic structural provisions for the implementation of the NAAQS.

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[1] See, *e.g.*, EPA's final rule on "National Ambient Air Quality Standards for Lead." 73 FR 66964 at 67034.

Ohio Revised Code (ORC) 3704.03 provides the Director of Ohio EPA with the authority to develop rules and regulations necessary to meet state and Federal ambient air quality standards. Ohio regulates directly emitted particulate matter through the rules in SIP-approved Ohio Administrative Code (OAC) Chapter 3745–17. Ohio also has SIP-approved rules regulating emissions of specific precursors to $PM_{2.5}$. For example, OAC 3745–14 provides for the direct regulation of nitrogen oxides (NO_X) emissions, and OAC 3745–18 provides for the direct regulation of sulfur dioxide (SO_2) emissions. EPA proposes that Ohio has met the infrastructure SIP requirements of section 110(a)(2)(A) with respect to the 2012 $PM_{2.5}$ NAAQS.

As previously noted, EPA is not, in this action, proposing to approve or disapprove any existing state provisions or rules related to SSM or director's discretion in the context of section 110(a)(2)(A).

B. Section 110(a)(2)(B)—Ambient Air Quality Monitoring/Data System

This section requires SIPs to include provisions to provide for establishing and operating ambient air quality monitors, collecting and analyzing ambient air quality data, and making these data available to EPA upon request. EPA determines that Ohio: (i) Monitors air quality at appropriate locations throughout the state using EPA-approved Federal Reference Methods or Federal Equivalent Method monitors; (ii) submits data to EPA's Air Quality System (AQS) in a timely manner; and, (iii) provides EPA Regional Offices with prior notification of any planned changes to monitoring sites or the network plan.

OEPA continues to operate an air monitoring network. EPA approved Ohio's 2015–2016 Annual Air Monitoring Network Plan, including the plan for $PM_{2.5}$. OEPA enters air monitoring data into AQS, and the state provides EPA with prior notification when changes to its monitoring sites or network plan are being considered. EPA proposes to find that Ohio has met the infrastructure SIP requirements of section 110(a)(2)(B) with respect to the 2012 $PM_{2.5}$ NAAQS.

C. Section 110(a)(2)(C)—Program for Enforcement of Control Measures; PSD

States are required to include a program providing for enforcement of all SIP measures and the regulation of construction of new or modified stationary sources to meet NSR requirements under PSD and NNSR programs. Part C of the CAA (sections 160–169B) addresses PSD, while part D of the CAA (sections 171–193) addresses NNSR requirements.

The evaluation of each state's submission addressing the infrastructure SIP requirements of section 110(a)(2)(C) covers: (i) Enforcement of SIP measures; (ii) PSD provisions that explicitly identify NO_X as a precursor to ozone in the PSD program; (iii) identification of precursors to $PM_{2.5}$ and accounting for condensables in the PSD program; (iv) $PM_{2.5}$ increments in the PSD program; and, (v) greenhouse gas (GHG) permitting and the "Tailoring Rule." [2]

Sub-Element (i): Enforcement of SIP Measures

Ohio EPA maintains an enforcement program to ensure compliance with SIP requirements. ORC 3704.03(R) provides the Director with the authority to enforce rules "consistent with the purpose of the air pollution control laws." SIP-approved ORC 3704.03 provides the Director with the authority to continue to implement Ohio's minor NSR and major source PSD program. EPA proposes that Ohio has met the SIP enforcement requirements of section 110(a)(2)(C) with respect to the 2012 $PM_{2.5}$ NAAQS.

Sub-Element (ii): PSD Provisions That Explicitly Identify NO_X as a Precursor to Ozone in the PSD Program

EPA's "Final Rule to Implement the 8-Hour Ozone National Ambient Air Quality Standard—Phase 2; Final Rule to Implement Certain Aspects of the 1990 Amendments Relating to New Source Review and Prevention of Significant Deterioration as They Apply in Carbon Monoxide, Particulate Matter, and Ozone NAAQS; Final Rule for Reformulated Gasoline" (Phase 2 Rule) was published on November 29, 2005 (*see* 70 FR 71612). Among other requirements, the Phase 2 Rule obligated states to revise their PSD programs to explicitly identify NO_X as a precursor to ozone (70 FR 71612 at 71679, 71699–71700).

The Phase 2 Rule required that states submit SIP revisions incorporating the requirements of the rule, including the specification of NO_X as a precursor to ozone provisions, by June 15, 2007 (70 FR 71612 at 71683).

EPA approved revisions to Ohio's PSD SIP reflecting these requirements on October 28, 2014 (79 FR 64119), and therefore, Ohio has met this set of infrastructure SIP requirements of section 110(a)(2)(C) with respect to the 2012 $PM_{2.5}$ NAAQS.

Sub-Element (iii): Identification of Precursors to $PM_{2.5}$ and Accounting for Condensables in the PSD Program

On May 16, 2008 (*see* 73 FR 28321), EPA issued the Final Rule on the "Implementation of the New Source Review (NSR) Program for Particulate Matter Less than 2.5 Micrometers ($PM_{2.5}$)" (2008 NSR Rule). The 2008 NSR Rule finalized several new requirements for SIPs to address sources that emit direct $PM_{2.5}$ and other pollutants that contribute to secondary $PM_{2.5}$ formation. One of these requirements is for NSR permits to address pollutants responsible for the secondary formation of $PM_{2.5}$, otherwise known as precursors. In the 2008 NSR Rule, EPA identified precursors to $PM_{2.5}$ for the PSD program to be SO_2 and NO_X (unless the state demonstrates to the Administrator's satisfaction or EPA demonstrates that NO_X emissions in an area are not a significant contributor to that area's ambient $PM_{2.5}$ concentrations). The 2008 NSR Rule also specifies that VOCs are not considered to be precursors to $PM_{2.5}$ in the PSD program unless the state demonstrates to the Administrator's satisfaction or EPA demonstrates that emissions of VOCs in an area are significant contributors to that area's ambient $PM_{2.5}$ concentrations.

The explicit references to SO_2, NO_X, and VOCs as they pertain to secondary $PM_{2.5}$ formation are codified at 40 CFR 51.166(b)(49)(i)(*b*) and 40 CFR 52.21(b)(50)(i)(*b*). As part of identifying pollutants that are precursors to $PM_{2.5}$, the 2008 NSR Rule also required states to revise the definition of "significant" as it relates to a net emissions increase or the potential of a source to emit pollutants. Specifically, 40 CFR

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[2] In EPA's April 28, 2011, proposed rulemaking for infrastructure SIPS for the 1997 ozone and $PM_{2.5}$ NAAQS, we stated that each state's PSD program must meet applicable requirements for evaluation of all regulated NSR pollutants in PSD permits (*see* 76 FR 23757 at 23760). This view was reiterated in EPA's August 2, 2012, proposed rulemaking for infrastructure SIPs for the 2006 $PM_{2.5}$ NAAQS (*see* 77 FR 45992 at 45998). In other words, if a state lacks provisions needed to adequately address NO_X as a precursor to ozone, $PM_{2.5}$ precursors, condensable particulate matter, $PM_{2.5}$ increments, or the Federal GHG permitting thresholds, the provisions of section 110(a)(2)(C) requiring a suitable PSD permitting program must be considered not to be met irrespective of the NAAQS that triggered the requirement to submit an infrastructure SIP, including the 2010 NO_2 NAAQS.

51.166(b)(23)(i) and 40 CFR 52.21(b)(23)(i) define "significant" for $PM_{2.5}$ to mean the following emissions rates: 10 tpy of direct $PM_{2.5}$; 40 tpy of SO_2; and 40 tpy of NO_X (unless the state demonstrates to the Administrator's satisfaction or EPA demonstrates that NO_X emissions in an area are not a significant contributor to that area's ambient $PM_{2.5}$ concentrations). The deadline for states to submit SIP revisions to their PSD programs incorporating these changes was May 16, 2011 (*see* 73 FR 28321 at 28341).[3]

The 2008 NSR Rule did not require states to immediately account for gases that could condense to form particulate matter, known as condensables, in $PM_{2.5}$ and PM_{10} emission limits in NSR permits. Instead, EPA determined that states had to account for condensables in applicability determinations and in establishing emissions limitations for $PM_{2.5}$ and PM_{10} in PSD permits beginning on or after January 1, 2011. This requirement is codified in 40 CFR 51.166(b)(49)(i)(*a*) and 40 CFR 52.21(b)(50)(i)(*a*). Revisions to states' PSD programs incorporating the inclusion of condensables were required to be submitted to EPA by May 16, 2011 (*see* 73 FR 28321 at 28341).

EPA approved revisions to Ohio's PSD SIP reflecting these requirements on October 28, 2014 (79 FR 64119), and therefore Ohio has met this set of infrastructure SIP requirements of section 110(a)(2)(C) with respect to the 2012 $PM_{2.5}$ NAAQS.

Sub-Element (iv): $PM_{2.5}$ Increments in the PSD Program

On October 20, 2010, EPA issued the final rule on the "Prevention of Significant Deterioration (PSD) for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$)—Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentration (SMC)" (2010 NSR Rule). This rule established several components for making PSD permitting determinations for $PM_{2.5}$, including a system of "increments" which is the mechanism used to estimate significant deterioration of ambient air quality for a pollutant. These increments are codified in 40 CFR 51.166(c) and 40 CFR 52.21(c), and are included in Table 1 below.

TABLE 1—$PM_{2.5}$ INCREMENTS ESTABLISHED BY THE 2010 NSR RULE IN MICROGRAMS PER CUBIC METER

	Annual arithmetic mean	24-Hour max
Class I	1	2
Class II	4	9
Class III	8	18

The 2010 NSR Rule also established a new "major source baseline date" for $PM_{2.5}$ as October 20, 2010, and a new trigger date for $PM_{2.5}$ as October 20, 2011. These revisions are codified in 40 CFR 51.166(b)(14)(i)(*c*) and (b)(14)(ii)(*c*), and 40 CFR 52.21(b)(14)(i)(*c*) and (b)(14)(ii)(*c*). Lastly, the 2010 NSR Rule revised the definition of "baseline area" to include a level of significance of 0.3 micrograms per cubic meter, annual average, for $PM_{2.5}$. This change is codified in 40 CFR 51.166(b)(15)(i) and 40 CFR 52.21(b)(15)(i).

On October 28, 2014 (79 FR 64119), EPA finalized approval of the applicable PSD revisions for Ohio, therefore Ohio has met this set of infrastructure SIP requirements of section 110(a)(2)(C) with respect to the 2012 $PM_{2.5}$ NAAQS.

Sub-Element (v): GHG Permitting and the "Tailoring Rule"

With respect to Elements C and J, EPA interprets the CAA to require each state to make an infrastructure SIP submission for a new or revised NAAQS that demonstrates that the air agency has a complete PSD permitting program meeting the current requirements for all regulated NSR pollutants. The requirements of Element D(i)(II) may also be satisfied by demonstrating the air agency has a complete PSD permitting program correctly addressing all regulated NSR pollutants. Ohio has shown that it currently has a PSD program in place that covers all regulated NSR pollutants, including GHGs.

On June 23, 2014, the United States Supreme Court issued a decision addressing the application of PSD permitting requirements to GHG emissions. *Utility Air Regulatory Group* v. *Environmental Protection Agency*, 134 S.Ct. 2427. The Supreme Court said that EPA may not treat GHGs as an air pollutant for purposes of determining whether a source is a major source required to obtain a PSD permit. The Court also found that EPA could continue to require that PSD permits, otherwise required based on emissions of pollutants other than GHGs, contain limitations on GHG emissions based on the application of Best Available Control Technology (BACT).

In order to act consistently with its understanding of the Court's decision pending further judicial action to effectuate the decision, EPA is no longer applying EPA regulations that would require that SIPs include permitting requirements that the Supreme Court found impermissible. Specifically, EPA is not applying the requirement that a state's SIP-approved PSD program require that sources obtain PSD permits when GHGs are the only pollutant: (I) That the source emits or has the potential to emit above the major source thresholds, or (ii) for which there is a significant emissions increase from a modification (*see* 40 CFR 51.166(b)(48)(v)).

EPA will review the Federal PSD rules in light of the Supreme Court opinion. In addition, EPA anticipates that many states will revise their existing SIP-approved PSD programs in light of the Supreme Court's decision. The timing and content of subsequent EPA actions with respect to EPA regulations and state PSD program approvals are expected to be informed by additional legal process before the United States Court of Appeals for the District of Columbia Circuit. At this juncture, EPA is not expecting states to have revised their PSD programs for purposes of infrastructure SIP submissions and is only evaluating such submissions to assure that the state's program correctly addresses GHGs consistent with the Supreme Court's decision.

At present, Ohio's SIP is sufficient to satisfy elements C, D(i)(II), and J with respect to GHGs because the PSD permitting program previously approved by EPA into the SIP continues to require that PSD permits (otherwise required based on emissions of pollutants other than GHGs) contain limitations on GHG emissions based on the application of BACT. Although the approved Ohio PSD permitting program may currently contain provisions that are no longer necessary in light of the Supreme Court decision, this does not render the infrastructure SIP submission inadequate to satisfy elements C, (D)(i)(II), and J. The SIP contains the necessary PSD requirements at this time, and the application of those requirements is not impeded by the presence of other previously-approved provisions regarding the permitting of sources of GHGs that EPA does not consider necessary at this time in light of the Supreme Court decision.

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[3] EPA notes that on January 4, 2013, the U.S. Court of Appeals for the D.C. Circuit, in *Natural Resources Defense Council* v. *EPA*, 706 F.3d 428 (D.C. Cir.), held that EPA should have issued the 2008 NSR Rule in accordance with the CAA's requirements for PM_{10} nonattainment areas (Title I, Part D, subpart 4), and not the general requirements for nonattainment areas under subpart 1 (*Natural Resources Defense Council* v. *EPA*, No. 08–1250). As the subpart 4 provisions apply only to nonattainment areas, EPA does not consider the portions of the 2008 rule that address requirements for $PM_{2.5}$ attainment and unclassifiable areas to be affected by the court's opinion. Moreover, EPA does not anticipate the need to revise any PSD requirements promulgated by the 2008 NSR rule in order to comply with the court's decision. Accordingly, EPA's approval of Ohio's infrastructure SIP as to elements (C), (D)(i)(II), or (J) with respect to the PSD requirements promulgated by the 2008 implementation rule does not conflict with the court's opinion. The Court's decision with respect to the nonattainment NSR requirements promulgated by the 2008 implementation rule also does not affect EPA's action on the present infrastructure action. EPA interprets the CAA to exclude nonattainment area requirements, including requirements associated with a nonattainment NSR program, from infrastructure SIP submissions due three years after adoption or revision of a NAAQS. Instead, these elements are typically referred to as nonattainment SIP or attainment plan elements, which would be due by the dates statutorily prescribed under subpart 2 through 5 under part D, extending as far as 10 years following designations for some elements.

For the purposes of the 2012 $PM_{2.5}$ NAAQS infrastructure SIPs, EPA reiterates that NSR reform regulations are not within the scope of these actions. Therefore, we are not taking action on existing NSR reform regulations for Ohio. EPA approved Ohio's minor NSR program on January 22, 2003 (68 FR 2909), and since that date, OEPA and EPA have relied on the existing minor NSR program to ensure that new and modified sources not captured by the major NSR permitting programs do not interfere with attainment and maintenance of the 2012 $PM_{2.5}$ NAAQS.

Certain sub-elements in this section overlap with elements of section 110(a)(2)(D)(i) and section 110(a)(2)(J). These links will be discussed in the appropriate areas below.

D. Section 110(a)(2)(D)—Interstate Transport

Section 110(a)(2)(D)(i)(I) requires SIPs to include provisions prohibiting any source or other type of emissions activity in one state from contributing significantly to nonattainment, or interfering with maintenance, of the NAAQS in another state. EPA is not taking action on this infrastructure element in regards to the 2012 $PM_{2.5}$ NAAQS and will do so in a future rulemaking.

Section 110(a)(2)(D)(i)(II) requires SIPs to include provisions prohibiting any source or other type of emissions activity in one state from interfering with measures required to prevent significant deterioration of air quality or to protect visibility in another state.

EPA notes that Ohio's satisfaction of the applicable PSD requirements for the 2012 $PM_{2.5}$ NAAQS has been detailed in the section addressing section 110(a)(2)(C). EPA notes that the actions in that section related to PSD are consistent with the actions related to PSD for section 110(a)(2)(D)(i)(II), and they are reiterated below.

EPA has previously approved revisions to Ohio's SIP that meet certain requirements obligated by the Phase 2 Rule and the 2008 NSR Rule. These revisions included provisions that: (1) Explicitly identify NO_X as a precursor to ozone, (2) explicitly identify SO_2 and NO_X as precursors to $PM_{2.5}$, and (3) regulate condensable particulate matter in applicability determinations and in establishing emissions limits. EPA has also previously approved revisions to Ohio's SIP that incorporate the $PM_{2.5}$ increments and the associated implementation regulations including the major source baseline date, trigger date, and $PM_{2.5}$ significance level per the 2010 NSR Rule. Ohio's SIP contains provisions that adequately address the 2012 $PM_{2.5}$ NAAQS.

With regard to the applicable requirements for visibility protection of section 110(a)(2)(D)(i)(II), states are subject to visibility and regional haze program requirements under part C of the CAA (which includes sections 169A and 169B). The 2013 Memo states that these requirements can be satisfied by an approved SIP addressing reasonably attributable visibility impairment, if required, or an approved SIP addressing regional haze. In this rulemaking, EPA is not proposing to approve or disapprove Ohio's satisfaction of the visibility protection requirements of section 110(a)(2)(D)(i)(II) for the 2010 NO_2 or SO_2 NAAQs. Instead, EPA will evaluate Ohio's compliance with these requirements in a separate rulemaking.[4]

Section 110(a)(2)(D)(ii) requires each SIP to contain adequate provisions requiring compliance with the applicable requirements of section 126 and section 115 (relating to interstate and international pollution abatement, respectively).

Section 126(a) requires new or modified sources to notify neighboring states of potential impacts from the source. The statute does not specify the method by which the source should provide the notification. States with SIP-approved PSD programs must have a provision requiring such notification by new or modified sources. A lack of such a requirement in state rules would be grounds for disapproval of this element.

Ohio has provisions in its SIP-approved OAC Chapter 3745–31, which is consistent with 40 CFR 51.166(q)(2)(iv), requiring new or modified sources to notify neighboring states of potential negative air quality impacts, and has referenced this program as having adequate provisions to meet the requirements of section 126(a). EPA is proposing that Ohio has met the infrastructure SIP requirements of section 126(a) with respect to the 2012 $PM_{2.5}$ NAAQS. Ohio does not have any obligations under any other subsection of section 126, nor does it have any pending obligations under section 115. EPA, therefore, is proposing that Ohio has met all applicable infrastructure SIP requirements of section 110(a)(2)(D)(ii).

E. Section 110(a)(2)(E)—Adequate Resources

This section requires each state to provide for adequate personnel, funding, and legal authority under state law to carry out its SIP, and related issues. Section 110(a)(2)(E)(ii) also requires each state to comply with the requirements respecting state boards under section 128.

Sub-Element (i) and (iii): Adequate Personnel, Funding, and Legal Authority Under State Law To Carry Out Its SIP, and Related Issues

At the time of its submission, OEPA included its most recent biennial budget with its submittal, which details the funding sources and program priorities addressing the required SIP programs. OEPA has routinely demonstrated that it retains adequate personnel to administer its air quality management program, and Ohio's environmental performance partnership agreement with EPA documents certain funding and personnel levels at OEPA. As discussed in previous sections, ORC 3704.03 provides the legal authority under state law to carry out the SIP. EPA proposes that Ohio has met the infrastructure SIP requirements of these portions of section 110(a)(2)(E) with respect to the 2012 $PM_{2.5}$ NAAQS.

Sub-Element (ii): State Board Requirements Under Section 128 of the CAA

Section 110(a)(2)(E) also requires each SIP to contain provisions that comply with the state board requirements of section 128 of the CAA. That provision contains two explicit requirements: (1) That any board or body which approves permits or enforcement orders under this chapter shall have at least a majority of members who represent the public interest and do not derive any significant portion of their income from persons subject to permits and enforcement orders under this chapter, and (2) that any potential conflicts of interest by members of such board or body or the head of an executive agency with similar powers be adequately disclosed.

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[4] Ohio does have an approved regional haze plan for non-EGUs. Ohio's plan for EGUs relied on the Clean Air Interstate Rule that has been recently superseded by the Cross State Air Pollution Rule to which Ohio EGU sources are also subject.

OEPA does not have a board that has the authority to approve enforcement orders or permitting actions as outlined in section 128(a)(1) of the CAA; instead, this authority rests with the Director of OEPA. Therefore, section 128(a)(1) of the CAA is not applicable in Ohio.

Under section 128(a)(2), the head of the executive agency with the power to approve enforcement orders or permits must adequately disclose any potential conflicts of interest. In its June 7, 2013, submission, OEPA notes that EPA has previously approved provisions into Ohio's SIP addressing these requirements (*see* 46 FR 57490). Notably, ORC 102: Public Officers—Ethics contains provisions that require the Director of OEPA (and his/her delegate) to file an annual statement with the ethics committee including potential conflicts of interest; furthermore, this annual filing is subject to public inspection. Therefore, EPA proposes that Ohio has met the applicable infrastructure SIP requirements for this section of 110(a)(2)(E) for the 2012 $PM_{2.5}$ NAAQS.

F. Section 110(a)(2)(F)—Stationary Source Monitoring System

States must establish a system to monitor emissions from stationary sources and submit periodic emissions reports. Each plan shall also require the installation, maintenance, and replacement of equipment, and the implementation of other necessary steps, by owners or operators of stationary sources to monitor emissions from such sources. The state plan shall also require periodic reports on the nature and amounts of emissions and emissions-related data from such sources, and correlation of such reports by each state agency with any emission limitations or standards established pursuant to this chapter. Lastly, the reports shall be available at reasonable times for public inspection.

OEPA district offices and local air agencies are currently required to witness 50% of all source testing and review 100% of all tests. EPA-approved rules in OAC 3745–15 contain provisions for the submission of emissions reports, and OAC 3745–77 and OAC 3745–31 provide requirements for recordkeeping by sources. EPA recognizes that Ohio has routinely submitted quality assured analyses and data for publication, and therefore proposes that Ohio has met the infrastructure SIP requirements of section 110(a)(2)(F) with respect to the 2012 $PM_{2.5}$ NAAQS.

G. Section 110(a)(2)(G)—Emergency Powers

This section requires that a plan provide for authority that is analogous to what is provided in section 303 of the CAA, and adequate contingency plans to implement such authority. The 2013 Memo states that infrastructure SIP submissions should specify authority, vested in an appropriate official, to restrain any source from causing or contributing to emissions which present an imminent and substantial endangerment to public health or welfare, or the environment.

The regulations at OAC 3745–25 contain provisions which allow the Director of OEPA to determine the conditions that comprise air pollution alerts, warnings, and emergencies. Moreover, the rules contained in OAC 3745–25 provide the requirement to implement emergency action plans in the event of an air quality alert or higher. EPA proposes that Ohio has met the applicable infrastructure SIP requirements for this portion of section 110(a)(2)(G) with respect to the 2012 $PM_{2.5}$ NAAQS.

H. Section 110(a)(2)(H)—Future SIP Revisions

This section requires states to have the authority to revise their SIPs in response to changes in the NAAQS, availability of improved methods for attaining the NAAQS, or to an EPA finding that the SIP is substantially inadequate.

As previously mentioned, ORC 3704.03 provides the Director of OEPA with the authority to develop rules and regulations necessary to meet ambient air quality standards in all areas in the state as expeditiously as practicable, but not later than any deadlines applicable under the CAA. ORC 3704.03 also provides the Director of OEPA with the authority to develop programs for the prevention, and abatement of air pollution. EPA proposes that Ohio has met the infrastructure SIP requirements of section 110(a)(2)(H) with respect to the 2012 $PM_{2.5}$ NAAQS.

I. Section 110(a)(2)(I)—Nonattainment Area Plan or Plan Revisions Under Part D

The CAA requires that each plan or plan revision for an area designated as a nonattainment area meet the applicable requirements of part D of the CAA. Part D relates to nonattainment areas.

EPA has determined that section 110(a)(2)(I) is not applicable to the infrastructure SIP process. Instead, EPA takes action on part D attainment plans through separate processes.

J. Section 110(a)(2)(J)—Consultation With Government Officials; Public Notifications; PSD; Visibility Protection

The evaluation of the submission from Ohio with respect to the requirements of section 110(a)(2)(J) are described below.

Sub-Element (i): Consultation With Government Officials

States must provide a process for consultation with local governments and Federal Land Managers (FLMs) carrying out NAAQS implementation requirements.

OEPA actively participates in the regional planning efforts that include both the state rule developers as well as representatives from the FLMs and other affected stakeholders. The FLMs are also included in OEPA's interested party lists which provide announcements of draft and proposed rule packages. OAC 3745–31–06 is a SIP-approved rule which requires notification and the availability of public participation related to NSR actions; notification is provided to the general public, executives of the city or county where the source is located, other state or local air pollution control agencies, regional land use planning agencies, and FLMs. OAC 3704.03(K) is a SIP-approved rule that which requires giving reasonable public notice and conducting public hearings on any plans for the prevention, control, and abatement of air pollution that the Director of OEPA is required to submit to EPA. Additionally, Ohio is an active member of the Lake Michigan Air Director's Consortium (LADCO). Therefore, EPA proposes that Ohio has met the infrastructure SIP requirements of this portion of section 110(a)(2)(J) with respect to the 2012 $PM_{2.5}$ NAAQS.

Sub-Element (ii): Public Notification

Section 110(a)(2)(J) also requires states to notify the public if NAAQS are exceeded in an area and must enhance public awareness of measures that can be taken to prevent exceedances.

OEPA maintains portions of its Web site specifically for issues related to the 2012 $PM_{2.5}$ NAAQS.[5] The information contained in these pages includes background on the health effects of each of these pollutants, the areas of most concern, and the strategies that the state has been taking to address the elevated levels, if any, of the pollutants. OEPA also actively populates EPA's AIRNOW program, and prepares annual data reports from its complete monitoring network. EPA proposes that Ohio has met the infrastructure SIP requirements of this portion of section 110(a)(2)(J) with respect to the 2012 $PM_{2.5}$ NAAQS.

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[5] See *http://www.epa.ohio.gov/dapc/sip/sip.aspx.*

Sub-Element (iii): PSD

States must meet applicable requirements of section 110(a)(2)(C) related to PSD. Ohio's PSD program in the context of infrastructure SIPs has already been discussed in the paragraphs addressing section 110(a)(2)(C) and 110(a)(2)(D)(i)(II), and EPA notes that the actions for those sections are consistent with the actions for this portion of section 110(a)(2)(J).

Therefore, Ohio has met all of the infrastructure SIP requirements for PSD associated with section 110(a)(2)(J) for the 2012 $PM_{2.5}$ NAAQS.

Sub-Element (iv): Visibility Protection

With regard to the applicable requirements for visibility protection, states are subject to visibility and regional haze program requirements under part C of the CAA (which includes sections 169A and 169B). In the event of the establishment of a new NAAQS, however, the visibility and regional haze program requirements under part C do not change. Thus, we find that there is no new visibility obligation "triggered" under section 110(a)(2)(J) when a new NAAQS becomes effective. In other words, the visibility protection requirements of section 110(a)(2)(J) are not germane to infrastructure SIP for the 2012 $PM_{2.5}$ NAAQS.

K. Section 110(a)(2)(K)—Air Quality Modeling/Data

SIPs must provide for performing air quality modeling for predicting effects on air quality of emissions from any NAAQS pollutant and submission of such data to EPA upon request.

OEPA reviews the potential impact of major and some minor new sources, consistent with appendix W of 40 CFR parts 51 and 52 "Guidelines on Air Quality Models," as well as OEPA Engineering Guide 69. These modeling data are available to EPA upon request. The regulatory requirements related to PSD modeling can be found in SIP-approved rule OAC 3745–31–18. Ohio's authority to require modeling conducted by other entities, *e.g.*, applicants, and the state's authority to perform modeling for attainment demonstrations can be found in SIP-approved ORC 3704.03(F). EPA proposes that Ohio has met the infrastructure SIP requirements of section 110(a)(2)(K) with respect to the 2012 $PM_{2.5}$ NAAQS.

L. Section 110(a)(2)(L)—Permitting Fees

This section requires SIPs to mandate each major stationary source to pay permitting fees to cover the cost of reviewing, approving, implementing, and enforcing a permit.

OEPA implements and operates the title V permit program, which EPA approved on August 15, 1995 (60 FR 42045); revisions to the program were approved on November 20, 2003 (68 FR 65401). Additional rules that contain the provisions, requirements, and structures associated with the costs for reviewing, approving, implementing, and enforcing various types of permits can be found in ORC 3745.11. EPA proposes that Ohio has met the infrastructure SIP requirements of section 110(a)(2)(L) for the 2012 $PM_{2.5}$ NAAQS.

M. Section 110(a)(2)(M)—Consultation/Participation by Affected Local Entities

States must consult with and allow participation from local political subdivisions affected by the SIP. OEPA follows approved procedures for allowing public participation, consistent with OAC 3745–47, which is part of the approved SIP. Consultation with local governments is authorized through ORC 3704.03(B). OEPA provides a public participation process for all stakeholders that includes a minimum of a 30-day comment period and a public hearing for all SIP related actions. EPA proposes that Ohio has met the infrastructure SIP requirements of section 110(a)(2)(M) with respect to the 2012 $PM_{2.5}$ NAAQS.

IV. What action is EPA taking?

EPA is proposing to approve most elements of the submission from OEPA certifying that its current SIP is sufficient to meet the required infrastructure elements under sections 110(a)(1) and (2) for the 2012 $PM_{2.5}$ NAAQS. EPA's proposed actions for the state's satisfaction of infrastructure SIP requirements, by element of section 110(a)(2) are contained in the table below.

Element	2012 $PM_{2.5}$
(A): Emission limits and other control measures	A
(B): Ambient air quality monitoring and data system	A
(C): Program for enforcement of control measures	A
(D)1: Interstate Transport—Significant contribution	NA
(D)2: Interstate Transport–interfere with maintenance	NA
(D)3: PSD	A
(D)4: Visibility	NA
(D)5: Interstate and International Pollution Abatement	A
(E): Adequate resources	A
(E): State boards	A
(F): Stationary source monitoring system	A
(G): Emergency power	A
(H): Future SIP revisions	A
(I): Nonattainment area plan or plan revisions under part D	+
(J)1: Consultation with government officials	A
(J)2: Public notification	A
(J)3: PSD	A
(J)4: Visibility protection	+
(K): Air quality modeling and data	A
(L): Permitting fees	A
(M): Consultation and participation by affected local entities	A

In the above table, the key is as follows:

A	Approve.
NA	No Action/Separate Rulemaking.
+	Not germane to infrastructure SIPs.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: June 14, 2016.

Robert A. Kaplan,

Acting Regional Administrator, Region 5.

[FR Doc. 2016–14894 Filed 6–22–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R05–OAR–2011–0698; FRL–9948–00–Region 5]

Approval and Promulgation of Air Quality Implementation Plans; Indiana; Redesignation of the Indiana Portion of the Louisville Area to Attainment of the 1997 Annual Standard for Fine Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; supplemental.

SUMMARY: The Environmental Protection Agency (EPA) is issuing a supplement to its July 11, 2013, proposed approval of Indiana's request to redesignate the Indiana portion of the Louisville, Indiana-Kentucky, area to attainment for the 1997 annual national ambient air quality standard (NAAQS or standard) for fine particulate matter ($PM_{2.5}$). After EPA's proposed redesignation in 2013, an audit of the Kentucky monitoring program identified problems which invalidated monitoring data for 2012 and the beginning of 2013. Because of this invalid data, the area could not meet the requirement that the entire area must demonstrate attainment of the standard using the most current three years of data. This supplemental proposal provides new quality-assured, quality-controlled data for the most recent three years of data showing that the entire area attains the 1997 $PM_{2.5}$ standard. In the supplemental proposal EPA is proposing that the entire Louisville area is attaining the 1997 $PM_{2.5}$ NAAQS based on the most recent three years of data. EPA also discusses the maintenance plan out-year emission projections, and the Cross-State Air Pollution Rule (CSAPR) remanded budgets impact on the Louisville area—because the status of these issues has changed from the initial proposal to now. EPA is seeking comment only on the issues raised in this supplemental proposal, and is not re-opening for comment other issues raised in the July 11, 2013, proposed approval.

DATES: Comments must be received on or before July 25, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2011–0698 at *http://www.regulations.gov* or via email to *blakley.pamela@epa.gov*. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Carolyn Persoon, Environmental Engineer, Control Strategies Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–8290, *persoon.carolyn@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever "we," "us," or "our" is used, we mean EPA. This **SUPPLEMENTARY INFORMATION** section is arranged as follows:

I. What is the background for the supplemental proposal?
II. On what specific issues is EPA taking comment?
  A. Louisville Area Design Values for 2013–2015; Entire Area Monitoring Attainment
  B. Demonstration of Maintenance
  C. CAIR and CSAPR
III. Summary of Proposed Actions
IV. Statutory and Executive Order Reviews

I. What is the background for the supplemental proposal?

On June 16, 2011, the Indiana Department of Environmental Management (IDEM) submitted a request for EPA to approve the redesignation of the Indiana portion of the Louisville (KY-IN) (Madison Township, Indiana, Jefferson County, Kentucky and Clark and Floyd Counties, Indiana) nonattainment area to attainment of the 1997 $PM_{2.5}$ annual standard. Indiana's June 16, 2011, redesignation submittal contained complete, quality-assured and certified air monitoring data for the years 2008–2010.

On July 11, 2013, EPA proposed to determine that the Indiana portion of the Louisville area had met the requirements for redesignation under section 107(d)(3)(E) of the Clean Air Act (CAA) (78 FR 41735). This proposal was based upon our review of ambient air monitoring data from 2009–2011, and preliminary data from 2012. It contained several related actions.

First, EPA proposed to approve the request from IDEM to change the legal designation of the Indiana portion of the Louisville area from nonattainment to attainment for the 1997 annual $PM_{2.5}$ NAAQS. EPA also proposed to approve Indiana's $PM_{2.5}$ maintenance plan for the Indiana portion of the Louisville area as a revision to the Indiana state implementation plan (SIP) because the plan met the requirements of section 175A of the CAA. In addition, EPA proposed to approve emissions inventories for primary $PM_{2.5}$, and all its precursors as satisfying the requirement in section 172(c)(3) of the CAA for a comprehensive, current emission inventory. Finally, EPA proposed a motor vehicle emissions budget for the Indiana portion of the Louisville area. EPA did not receive adverse comments on the proposed rulemaking.

In August 2013, EPA issued results of a technical systems audit on the $PM_{2.5}$ laboratory in Kentucky, which invalidated the Jefferson County monitoring data for all of 2012, and a small portion of the monitoring data from 2013 (a portion of the first quarter). See the docket for the technical systems audit information. Since the area could no longer demonstrate attainment of the standard for the entire area, EPA did not finalize its proposal. Kentucky began collecting valid data in early 2013 (the end of the first quarter) after the monitoring audit issues had been addressed, resulting in a valid design value for the area using 2013–2015 data. Both Indiana and Kentucky certified valid data for 2015 in the beginning of 2016. EPA has approved the use of this quality-assured, quality-controlled certified complete data for use in regulatory actions.

Today, EPA is publishing a supplement to its July 11, 2013, proposed rulemaking. The supplement is based on valid design values for the 2013–2015 period, demonstrating attainment of the standard for the entire Louisville area using the most recent three years of data. Preliminary data for 2016 shows that the entire Louisville area continues to attain the standard. This proposal also discusses the maintenance plan emission projections of 2025 and the impact of the budgets remanded under CSAPR on the Louisville area because the status of these issues has changed from the initial proposal.

II. On what specific issues is EPA taking comments?

In this portion of EPA's supplemental proposal, EPA is soliciting comment on the limited issue of the 2013–2015 design values demonstrating attainment of the standard for the entire Louisville area, the maintenance plan emission projections for 2025, and the impact on the Louisville area of the 2015 D.C. Circuit decision remanding certain CSAPR budgets.

A. Louisville Area Design Values for 2013–2015; Entire Area Monitoring Attainment

EPA is proposing to determine that the Louisville area is attaining the 1997 annual $PM_{2.5}$ NAAQS based upon the most recent three years of complete, certified and quality-assured data. Under EPA's regulations at 40 CFR 50.7, the annual primary and secondary $PM_{2.5}$ standards are met when the annual arithmetic mean concentration, as determined in accordance with 40 CFR part 50, appendix N, is less than or equal to 15.0 micrograms per cubic meter(µg/m^3)at all monitoring sites in the area. Data are considered to be sufficient for comparison to the NAAQS if three consecutive complete years of data exist. A complete year of air quality data is comprised of four calendar quarters, with each quarter containing data from at least 75% capture of the scheduled sampling days. In this case, the 2009–2011 values were calculated prior to the audit invalidating data collected in the Kentucky portion of Louisville for 2012 and beginning of 2013 (portion of the first quarter). The 2013–2015 values are based on quality-assured, quality-controlled, certified complete data, and only included valid data collected after the audit issues were corrected. Preliminary data for 2016 shows the area continues to attain the standard. The Louisville design value for the most current three years of data is 11.7 µg/m^3.

TABLE 1—THE 1997 ANNUAL $PM_{2.5}$ DESIGN VALUES FOR THE LOUISVILLE MONITOR WITH COMPLETE DATA FOR THE 2009–2011,[1] AND 2013–2015 DESIGN VALUE IN µg/m^3

County	Site	Design value 2009–2011 (µg/m^3)	Design value 2013–2015 (µg/m^3)
Clark County, IN	180190006	13.5	11.4
Clark County, IN	180190008	11.4	9.3
Floyd County, IN	180431004	12.3	10.0
Jefferson County, KY	211110043	12.6	11.3
Jefferson County, KY	211110051	12.7	11.7
Jefferson County, KY	211110067	12.1	10.5

[1] 2009–2011 design values are the desigh values for the area prior to date issues, and design values for 2013–2015 are the most recent three years of monitoring data showing that the area is attaining the standard.

Data recorded at monitors in 2013, 2014, and 2015 are considered valid and were collected after corrective actions resulting from the technical systems audit. These are the data on which EPA is basing its decision that the Louisville area has attained the 1997 annual $PM_{2.5}$ NAAQS.

B. Demonstration of Maintenance

Along with the redesignation request, Indiana submitted a revision to its $PM_{2.5}$ SIP to include a maintenance plan for the Indiana portion of the Louisville area, as required by section 175A of the CAA. Indiana's plan demonstrates maintenance of the 1997 annual $PM_{2.5}$ standard through 2025 by showing that current and future emissions of oxides of nitrogen (NO_X), directly emitted $PM_{2.5}$, and sulfur dioxide (SO_2) in the area remain at or below attainment year emission levels. Section 175A requires a state seeking redesignation to attainment to submit a SIP revision which provides for the maintenance of the NAAQS in the area "for at least 10 years after the redesignation." See September 4, 1992, memorandum from John Calcagni, entitled "Procedures for Processing Requests to Redesignate Areas to Attainment," p. 9. Where the emissions inventory method of showing maintenance is used, its purpose is to show that emissions during the maintenance period will not increase over the attainment year inventory. Calcagni Memorandum, pp. 9–10.

As discussed in detail in the section below, the state's maintenance plan submission expressly documents that the area's emissions inventories will remain below the attainment year inventories through 2025. In addition, for the reasons set forth below, EPA believes that the state's submission, in conjunction with additional supporting information, further demonstrates that the area will continue to maintain the $PM_{2.5}$ standard at least through 2026. Thus, if EPA finalizes its proposed approval of the redesignation request and maintenance plan in 2016, it will be based on a showing, in accordance with section 175A, that the state's maintenance plan provides for maintenance for at least ten years after redesignation.

Indiana's plan demonstrates maintenance of the 1997 annual $PM_{2.5}$ NAAQS through 2025 by showing that current and future emissions of NO_X, directly emitted $PM_{2.5}$ and SO_2 for the area remain at or below attainment year emission levels.

The rate of decline in emissions of $PM_{2.5}$, NO_X, and SO_2 from the attainment year 2008 through 2025 (calculated from Table 2) indicates that emissions inventory levels not only significantly decline between 2008 and 2025, but that the reductions will continue in 2026 and beyond. The average annual rate of decline is 4,472 tons per year (tpy) for SO_2, 1,052 tpy of NO_X, and 8.73 tpy of direct PM for the Indiana portion of the Louisville area, and average annual rate of decline is 4,436 tpy for SO_2, 2,239 tpy of NO_X, and 98.1 tpy of direct PM for the entire Louisville area. These rates of decline are consistent with monitored and projected air quality trends, emissions reductions achieved through emissions controls and regulations that will remain in place beyond 2026 and through fleet turnover that will continue beyond 2026, among other factors. We are proposing to find the mobile source contribution to these emissions is expected to remain insignificant in 2026 and beyond because of fleet turnover in upcoming years that will result in cleaner vehicles and cleaner fuels.

A maintenance demonstration need not be based on modeling. *See Wall* v. *EPA,* 265 F.3d 426 (6th Cir. 2001), *Sierra Club* v. *EPA,* 375 F. 3d 537 (7th Cir. 2004). *See also* 66 FR 53094, 53099–53100 (October 19, 2001), 68 FR 25413, 25430–25432 (May 12, 2003), 78 FR 53272 (August 29, 2013). Indiana uses emissions inventory projections for the years 2015 and 2025 to demonstrate maintenance for the entire Louisville area. The projected emissions were estimated by Indiana, with assistance from the Lake Michigan Air Directors Consortium (LADCO) and the Kentucky Regional Planning and Development Agency (KIPDA), who used the MOVES2010a model for mobile source projections. Projection modeling of inventory emissions was done for the 2015 interim year emissions using estimates based on the 2008 and 2015 LADCO modeling inventory, using LADCO's growth factors, for all sectors. The 2025 maintenance year emission estimates were based on emissions estimates from the 2015 LADCO modeling. Table 2 shows the 2008 attainment base year emission estimates and the 2015 and 2025 emission projections for the Louisville area, taken from Indiana's June 16, 2011, submission.

TABLE 2—COMPARISON OF 2008, 2015 AND 2025 NO_X, DIRECT $PM_{2.5}$ AND SO_2 EMISSION TOTALS (tpy) FOR THE LOUISVILLE AREA

	SO_2	NO_X	$PM_{2.5}$
2008 (baseline)	151,503.01	97,533.93	6,724.02.
2015	76,958.54	69,936.67	5,540.29.
2025	76,082.07	59,455.17	5,055.61.
Change 2008–2025	−75,420.94 50% decrease	−38,078.76 39% decrease	−1,668.41. 25% decrease.

Table 2 shows that, for the period between 2008 and the maintenance projection for 2025, the Louisville area will reduce NO_X emissions by 38,078 tpy; direct $PM_{2.5}$ emissions by 1,668 tpy; and SO_2 emissions by 75,420 tpy. The 2025 projected emissions levels are significantly below attainment year inventory levels, and, based on the rate of decline, it is highly improbable that any increases in these levels will occur in 2026 and beyond. Thus, the emissions inventories set forth in Table 2 show that the area will continue to maintain the annual $PM_{2.5}$ standards during the maintenance period and at least through 2026.

As Table 1 and 2 demonstrate, monitored $PM_{2.5}$ design value concentrations in the Louisville area are well below the NAAQS in the years beyond 2008, an attainment year for the area. Further, those values are trending downward as time progresses. Based on the future projections of emissions in 2025 showing significant emissions reductions in direct $PM_{2.5}$, NO_X, and SO_2, it is very unlikely that monitored $PM_{2.5}$ values in 2026 and beyond will show violations of the NAAQS. Additionally, the 2013–2015 design value of 11.7 µg/m³ provides a sufficient margin for the 1997 standard in the unlikely event emissions rise slightly in the future.

C. CAIR and CSAPR

In its redesignation request and maintenance plan, the state identified the Clean Air Interstate Rule (CAIR) as a permanent and enforceable measure that contributed to attainment in the Louisville Area. CAIR created regional cap-and-trade programs to reduce SO_2 and NO_X emissions in 27 eastern states, including Indiana, that contributed to downwind nonattainment or interfered with maintenance of the 1997 8-hour ozone NAAQS and the 1997 $PM_{2.5}$ NAAQS. *See* 70 FR 25162 (May 12, 2005). Indiana adopted CAIR budgets into its SIP on November 1, 2006, with emission reductions beginning in 2010 and extending into 2015. By 2007, the beginning of the attainment time period identified by Indiana, CAIR had begun achieving emission reductions in the state.

In 2008, the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) vacated CAIR, *North Carolina* v. *EPA,* 531 F.3d 896 (D.C. Cir. 2008); but ultimately remanded the rule to EPA without vacatur to preserve the environmental benefits provided by CAIR, *North Carolina* v. *EPA,* 550 F.3d 1176, 1178 (D.C. Cir. 2008). On August 8, 2011 (76 FR 48208), acting on the D.C. Circuit's remand, EPA promulgated CSAPR to replace CAIR and, thus, to address the interstate transport of emissions contributing to nonattainment and interfering with maintenance of the two air quality standards covered by CAIR as well as the 2006 $PM_{2.5}$ NAAQS. CSAPR requires substantial reductions of SO_2 and NO_X emissions from emission generating units (EGUs) in 28 states in the eastern United States. As a general matter, because CSAPR is CAIR's replacement, emissions reductions associated with CAIR will for most areas be made permanent and enforceable through implementation of CSAPR.

Numerous parties filed petitions for review of CSAPR in the D.C. Circuit, and on August 21, 2012, the court issued its ruling, vacating and remanding CSAPR to EPA and ordering continued implementation of CAIR. *EME Homer City Generation, L.P.* v. *EPA,* 696 F.3d 7, 38 (D.C. Cir. 2012). The D.C. Circuit's vacatur of CSAPR was reversed by the United States Supreme Court on April 29, 2014, and the case was remanded to the D.C. Circuit to resolve remaining issues in accordance with the high court's ruling. *EPA* v. *EME*

Homer City Generation, L.P., 134 S. Ct. 1584 (2014). On remand, the D.C. Circuit affirmed CSAPR in most respects, but invalidated without vacating some of the CSAPR budgets as to a number of states. *EME Homer City Generation, L.P.* v. *EPA*, 795 F.3d 118 (D.C. Cir. 2015) (*EME Homer City II*). The Phase 2 annual and ozone season NO_X and SO_2 budgets for Indiana are not affected by the Court's decision. The litigation over CSAPR ultimately delayed implementation of that rule for three years, from January 1, 2012, when CSAPR's cap-and-trade programs were originally scheduled to replace the CAIR cap-and-trade programs, to January 1, 2015. CSAPR's Phase 2 budgets were originally promulgated to begin on January 1, 2014, and are now scheduled to begin on January 1, 2017. CSAPR will continue to operate under the existing emissions budgets until EPA addresses the D.C. Circuit's remand. The Court's decision did not affect Indiana's CSAPR emissions budgets; therefore, CSAPR ensures that the NO_X and SO_2 emissions reductions associated with CAIR and CSPAR throughout Indiana are permanent and enforceable.[1]

In its redesignation request, Indiana noted that a number of states contributed to $PM_{2.5}$ concentrations in the Louisville area based on EPA air quality modeling. Additionally, an air quality modeling analysis conducted by IDEM demonstrates that the Louisville area would be able to attain the $PM_{2.5}$ standard even in the absence of either CAIR or CSAPR. See appendices H and I of Indiana's redesignation request found in the docket. This modeling is available in the docket for this proposed redesignation action.

To the extent that Louisville relies on CSAPR for maintenance of the standard, EPA has identified the Louisville area as having been significantly impacted by pollution transported from other states in both CAIR and CSAPR, and these rules greatly reduced the tons of SO_2 and NO_X emissions generated in the states upwind of the area. The air quality modeling performed for the CSAPR rulemaking identified the following states as having contributed to $PM_{2.5}$ concentrations in the Louisville area: Illinois, Indiana, Kentucky, Michigan, Missouri, Ohio, Pennsylvania, Tennessee, West Virginia and Wisconsin. *See* 76 FR 48208(August 8, 2011). Even though the first phase of CAIR implementation for SO_2 did not begin until 2010, many sources began reducing their emissions well in advance of the first compliance deadline because of the incentives offered by CAIR for early compliance with the rule. The emission reductions in the states upwind of the Louisville area achieved by CAIR, and made permanent by CSAPR, are unaffected by the D.C. Circuit's remand of CSAPR.[2]

III. Summary of Proposed Actions

EPA is issuing a supplement to its action, published July 11, 2013, which proposed to redesignate the Indiana portion of the Louisville area to attainment for the 1997 annual $PM_{2.5}$ NAAQS, to approve the associated maintenance plan, and to approve the state's emission inventory. EPA is concluding that the most current three year design values show that the area is attaining the standard and preliminary values show the area continues to attain the 1997 annual $PM_{2.5}$ NAAQS. EPA also determined that the projections used in the states submittal meet the requirements of the maintenance plan out-year emission projections. EPA concluded that the CSAPR remanded budgets did not affect the area's ability to attain through permanent and enforceable measures and will not affect the area's ability to maintain the standard. EPA is seeking comment only on the issues raised in this supplemental proposal, and is not re-opening comment on other issues addressed in its prior proposal.

IV. Statutory and Executive Order Reviews

Under the CAA, redesignation of an area to attainment and the accompanying approval of a maintenance plan under section 107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those imposed by state law. A redesignation to attainment does not in and of itself create any new requirements, but rather results in the applicability of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, these proposed actions do not impose additional requirements beyond those imposed by state law and the CAA. For that reason, these proposed actions:

- Are not "significant regulatory actions" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Are certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Do not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Are not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Do not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because a determination of attainment is an action that affects the status of a geographical area and does not impose any new regulatory requirements on tribes, impact any existing sources of air pollution on tribal lands, nor impair the maintenance of ozone national ambient air quality standards in tribal lands.

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter.

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[1] 2009–2011 design values are the design values for the area prior to data issues, and design values for 2013–2015 are the most recent three years of monitoring data showing that the area is attaining the standard.

[2] The D.C. Circuit in *EME Homer City II* remanded the SO_2 trading program budgets for four states, none of which were identified as contributing to the Louisville area. Moreover, updated air quality modeling performed for the CSAPR identified that the Louisville area can attain and maintain the 1997 $PM_{2.5}$ NAAQS and no modeled issues for the 2012 NAAQS 76 FR 48207, 48241 (August 8, 2011) and Page memo, March 17, 2016.

40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: June 1, 2016.

Robert A. Kaplan,

Acting Regional Administrator, Region 5.

[FR Doc. 2016–14806 Filed 6–22–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[150306232–6491–01]

RIN 0648–BE96

Fisheries of the Northeastern United States; Monkfish; Framework Adjustment 9

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: We are proposing to approve and implement regulations submitted by the New England and Mid-Atlantic Fishery Management Councils in Framework Adjustment 9 to the Monkfish Fishery Management Plan. This action is necessary to better achieve the goals and objectives of the management plan and achieve optimum yield. The proposed action is intended to enhance the operational and economic efficiency of existing management measures and increase monkfish landings.

DATES: Public comments must be received by July 8, 2016.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2015–0045, by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2015-0045*, click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to John K. Bullard, Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930–2276. Mark the outside of the envelope: "Comments on Monkfish Framework 9."

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

New England Fishery Management Council staff prepared an environmental assessment (EA) for Monkfish Framework Adjustment 9 that describes the proposed action and other considered alternatives. The EA provides a thorough analysis of the biological, economic, and social impacts of the proposed measures and other considered alternatives, a preliminary Regulatory Impact Review, and economic analysis. Copies of the Framework 9 EA are available on request from Thomas A. Nies, Executive Director, New England Fishery Management Council, 50 Water Street, Newburyport, MA 01950. This document is also available from the following internet addresses: *http://www.greateratlantic.fisheries.noaa.gov/* or *http://www.nefmc.org.*

FOR FURTHER INFORMATION CONTACT: Allison Murphy, Fishery Policy Analyst, (978) 281–9122.

SUPPLEMENTARY INFORMATION:

Background

The monkfish fishery is jointly managed under the Monkfish Fishery Management Plan (FMP) by the New England and the Mid-Atlantic Fishery Management Councils. The fishery extends from Maine to North Carolina from the coast out to the end of the continental shelf. The Councils manage the fishery as two management units, with the Northern Fishery Management Area (NFMA) covering the Gulf of Maine (GOM) and northern part of Georges Bank (GB), and the Southern Fishery Management Area (SFMA) extending from the southern flank of GB through Southern New England (SNE) and into the Mid-Atlantic (MA) Bight to North Carolina.

Monkfish are often caught while fishing for Northeast (NE) multispecies, particularly in the NFMA. This has resulted in two closely related fisheries as a majority of monkfish vessels operating in the NFMA are issued both monkfish and NE multispecies permits. Because this action proposes to modify some requirements for NE multispecies sector vessels, it is also considered Framework Adjustment 54 to the NE Multispecies FMP.

The monkfish fishery is primarily managed by landing limits and a yearly allocation of monkfish days-at-sea (DAS) calculated to enable vessels participating in the fishery to catch, but not exceed, the target total allowable landings (TAL) and the annual catch target (ACT, the TAL plus an estimate of expected discards) in each management area. Both the ACT and the TAL are calculated to maximize yield in the fishery over the long term. Based on a yearly evaluation of the monkfish fishery, the Councils may revise existing management measures through the framework provisions of the FMP, including DAS allocations and landing limits, to better achieve the goals and objectives of the FMP and achieve optimum yield (OY), as required by the Magnuson-Stevens Fishery Conservation and Management Act. Amendment 5 (76 FR 30265; May 25, 2011) defined OY as fully harvesting the ACT.

We completed an operational stock assessment in May 2013 to update the state of the monkfish stocks and provide projections to assist with setting future catch levels. The 2013 assessment update revised existing biological reference points, including a substantial reduction in the overfishing level, and concluded that the two monkfish stocks are neither overfished nor subject to overfishing.

The monkfish fishery has failed to fully harvest the available ACT each year since 2011, particularly in the NFMA where the under-harvest has been more substantial. As a result, the fishery has not been achieving OY in either area in recent years. The Councils developed Framework 9 to enhance the operational efficiency of existing management measures in an effort to better achieve OY.

Proposed Measures

1. Monkfish Possession Limits in the NFMA

This action would revise monkfish possession limits specified in 50 CFR 648.94 to help increase monkfish landings and better achieve the ACT caught in the NFMA. Specifically, this measure would eliminate the monkfish possession limit for monkfish Category C and D permitted vessels (referred to as Category C and D vessels in this section) fishing under both a NE multispecies and monkfish day-at-sea (DAS) in the NFMA.

Possession limits differ based on the type of DAS being used by a vessel. Table 1 includes a summary of the current monkfish tail weight possession limits for a vessel fishing under the various DAS available in the NFMA. We are proposing to add another tier to the possession limit system without changing the existing possession limits for a vessel fishing on a NE multispecies DAS or a monkfish DAS. We propose to allow a Category C or D vessel that is fishing under both a NE multispecies and a monkfish DAS in the NFMA to retain an unlimited amount of monkfish (Table 1).

TABLE 1—PROPOSED AND EXISTING MONKFISH TAIL WEIGHT POSSESSION LIMITS FOR MONKFISH CATEGORY C AND D PERMITTED VESSELS FISHING ON A DAS IN THE NFMA

	DAS type	Category C possession limit	Category D possession limit
Existing Measures	NE Multispecies A DAS only	600 lb (272.16 kg)	500 lb (226.80 kg).
	Monkfish DAS only	1,250 lb (566.99 kg)	600 lb (272.16 kg).
Proposed Measure	NE Multispecies A and Monkfish DAS	Unlimited	Unlimited.

Note: Tail weight × 2.91 = whole weight.

As is currently the case, a Category C or D vessel would still be required to declare a trip at the dock under a NE multispecies A DAS with the option to declare a monkfish-DAS while at sea, and then declare a monkfish DAS while at sea in order or to be exempt from the monkfish possession limits. Alternately, a Category C or D vessel would be required to declare a concurrent NE Multispecies A DAS and a monkfish DAS at the dock prior to starting a trip in order or to be exempt from the monkfish possession limits. Under existing regulations, however, a Category C or D vessel cannot begin a trip under a monkfish-only DAS and add a NE Multispecies A DAS while at sea in order or to be exempt from the monkfish possession limit. A provision to allow this and provide this flexibility is also considered in this proposed rule and discussed in detail below. Without this change, a Category C or D vessel that does not declare a trip under a NE multispecies A DAS and a monkfish DAS (or option to declare a monkfish DAS while at sea) at the dock prior to starting a trip would not be exempt from the monkfish possession limits under this action. In such cases, the existing monkfish possession limits for Category C and D vessels fishing only under a NE multispecies DAS or a monkfish DAS would remain the same, as outlined in Table 1.

2. NE Multispecies DAS Declaration Requirements

This action would revise NE multispecies DAS declaration requirements to help increase operational flexibility and potentially increase monkfish landings in the NFMA. Functionally, this would allow a Monkfish Category C and D vessel enrolled in a NE multispecies sector (referred to as a Category C and D sector vessel in this section) fishing in the NFMA to declare a NE multispecies A DAS while at sea, through the vessel monitoring system (VMS), when certain conditions apply.

We propose to allow a Category C and D sector vessel fishing on either a NE multispecies non-DAS sector trip or a monkfish-only DAS exclusively in the NFMA to declare a NE multispecies A DAS while at sea. Currently, a Category C or D sector vessel that is not declared into the monkfish fishery, but is declared into the NE multispecies fishery on a non-DAS sector trip, is limited to an incidental possession limit for monkfish. In the NFMA, which overlaps with the GOM and GB Regulated Mesh Areas (RMAs), the incidental monkfish possession limit is up to 5 percent of total weight of fish on board.

This measure would also increase flexibility by allowing a vessel to fish in a larger geographic area. Currently, any Category C or D vessel must use its monkfish-only DAS exclusively in a monkfish exempted fishery. An exempted fishery is an area and season demonstrated to have minimal bycatch of NE multispecies when using a specific type of gear. The only monkfish exempted fishery that overlaps with the NFMA is in the Gulf of Maine/Georges Bank Dogfish and Monkfish Gillnet Exemption Area, as described in § 648.80(a)(13). Allowing a vessel to declare a NE multispecies DAS while at sea would allow that vessel to fish outside of these specified areas and retain NE multispecies for the remainder of the trip.

Under this proposed measure, monkfish possession limits would increase from the incidental monkfish possession limit to the monkfish possession limits for Category C and D sector vessels fishing on a NE multispecies A DAS in the NFMA, as summarized in Table 2. We are also proposing to allow a Category C or D sector vessel fishing exclusively in the GOM/GB Dogfish and Monkfish Gillnet Exemption Area to change its VMS declaration from a monkfish-only DAS to a combined monkfish and NE multispecies A DAS while at sea. Under this proposed measure, monkfish possession limits for Category C and D sector vessels would become unlimited, as described in Table 2, should we also approve changes to the possession limits described above.

TABLE 2—PROPOSED AND EXISTING MONKFISH TAIL WEIGHT POSSESSION LIMITS FOR MONKFISH CATEGORY C AND D SECTOR VESSELS FISHING ON A DAS IN THE NFMA

	DAS type	Category C possession limit	Category D possession limit
Existing Measures	No DAS	up to 5 percent of total weight of fish on board.	up to 5 percent of total weight of fish on board.
	NE Multispecies A DAS only	600 lb (272.16 kg)	500 lb (226.80 kg).
	Monkfish DAS only	1,250 lb (566.99 kg)	600 lb (272.16 kg).
Proposed Measure	NE Multispecies A and Monkfish DAS	Unlimited	Unlimited.

While we are proposing this measure as recommended by the Councils, we have some concerns. First, our analyses suggest that the necessary implementation costs may not exceed the benefits to the fishery. This measure will require VMS software modifications to allow vessels the ability to declare a NE multispecies A DAS while at sea. We expect this VMS change to cost roughly $100,000, based on other, recent VMS software changes we have implemented. The cost associated with VMS changes is primarily because 4 approved vendors for the Greater Atlantic Region will all be required to update their software onboard vessels using their VMS equipment. This cost is borne solely by the Agency. The EA for Framework 9 identified only a small percent (1.6 percent) of vessels that approached applicable trip limits for non-DAS sector trips and monkfish-only trips. In addition, the Framework 9 EA indicates that few trips would have yielded additional monkfish landings in recent fishing years had the proposed NE multispecies DAS at-sea declaration change been in place. Based on this information, this measure may do little to help the fishery achieve optimum yield. We are interested in public comment on the cost, effectiveness, and utility of this proposed measure. We intend to further evaluate the potential cost/benefit of providing this at-sea declaration flexibility, as well as public comment, when considering the approvability of this measure.

Proposing to allow Category C and D sector vessels fishing on a monkfish-only DAS in the NFMA to declare a NE multispecies A DAS while at sea may not provide as many benefits as first anticipated. As described above, only the GOM/GB Dogfish and Monkfish Gillnet Exemption overlaps with the NFMA. This exempted fishery is open from July 1 through September 14, annually, for a vessel using gillnet gear in the waters of Cape Cod Bay and off southern Maine. Given that the majority of the fleet in the NFMA fishes with trawl gear and cannot take advantage of monkfish-only DAS because they are excluded from this exempted fishery, we are concerned that only a small number of vessels that use gillnet gear would benefit from this flexibility.

Second, allowing a vessel to declare a NE multispecies A DAS after starting a trip on a monkfish-only DAS could potentially circumvent existing NE multispecies pre-trip notification requirements for deploying industry-funded at-sea monitors. We believed, at the time the Council took final action, that limiting the declaration change to sector vessels would mitigate these concerns. Since Council final action, we have continued to discuss the nuances of this potential provision with Regional Office NE multispecies and Northeast Fisheries Science Center, Fishery Sampling Branch staff. We remain concerned that the ability to switch from a monkfish-only DAS to a NE multispecies A DAS would allow vessels to bypass sector monitoring and reporting requirements.

A potential remedy to this loophole is an alternative that would require a vessel to comply with existing pre-trip notification requirements at § 648.11(k) and be subject to sector-funded at-sea monitoring to be able to change declarations at-sea. In addition, we could also require a vessel to submit a sector trip-start hail, described at § 648.10(k)(1)(iii), so that we can identify trips that may use this declaration flexibility.

We recognize that this potential solution may be somewhat less flexible than what was intended by the Councils and was not explicitly contemplated or discussed by the Councils. However, if not imposed, the proposed measures, as recommended, would allow vessels to circumvent sector-related reporting requirements, and inclusion of these measures pursuant to the authority provided to the Secretary of Commerce in section 305(d) of the Magnuson-Stevens Act may therefore be necessary to implement this portion of Framework 9 consistently with the Act. Adding NE multispecies monitoring requirements on these trips could complicate the Northeast Fisheries Observer Program and At-Sea Monitoring Program sea-day schedule assignments, coverage accomplishments, and future coverage needs. Further, fewer fishermen may use the flexibility option if they are at risk of being assigned an at-sea monitor, which industry has to pay for. We are soliciting specific comment from the Councils and the public on both the at-sea declaration flexibility as recommended by the Councils and this potential solution.

If this remedy solution is approved, the pre-trip notification system (PTNS) must be modified to accept monkfish-only trips. Currently, PTNS will only accept trips declared into the NE multispecies (*i.e.,* non-DAS sector trips and A DAS trips) and Squid, Mackerel, and Butterfish fisheries. Monkfish-only trips would need to be added to the system and assigned a selection protocol. We are unsure about the associated costs for such a change.

Finally, we have some enforcement concerns with the proposal to allow Category C and D sector vessels fishing on a monkfish-only DAS in the NFMA to declare a NE multispecies A DAS while at sea. Currently, a Category C or D sector vessel fishing on a monkfish-only DAS in an exempted fishery is required to discard all NE multispecies. Similarly, a Category C or D sector vessel fishing on a NE multispecies A DAS or on a non-DAS sector trip is currently required to retain all legal-sized groundfish. Should this measure be approved, a Category C or D sector vessel would begin a trip discarding all NE multispecies, and then be required to retain all legal-sized NE multispecies, once the vessel declares a NE multispecies DAS. This may introduce confusion about discarding and catch reporting requirements for the industry and complicates the enforceability of this measure. To help provide clarity, pursuant to the authority provided to the Secretary of Commerce in sector 305(d) of the Magnuson-Stevens Act, we could revise the sector discard and operations plan prohibitions at § 648.14(k)(14)(iv) and (viii) and the sector monitoring requirements at § 648.87(b)(1)(v)(A) to make clear that there would be different discard requirements before and after a vessel declares a NE multispecies DAS. We are also soliciting specific comment from the Councils and the public on clarifying the discard requirements.

It should be noted that we may need to delay effectiveness of this measure, should it be approved. Modifications to VMS would likely take months to complete and we are uncertain how long the necessary PTNS changes may take to implement.

3. Minimum Mesh Size Requirements in the SFMA

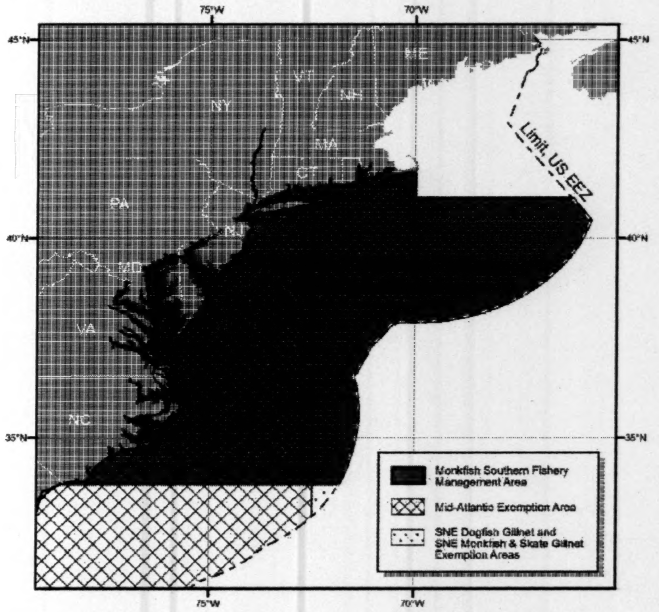
We are proposing to revise minimum mesh size requirements at § 648.80(b) and (c) and § 648.91(c)(1)(iii) to increase operational flexibility. The changes would allow vessels to target both monkfish and dogfish while on the same trip. Currently, the following restrictions apply in the SFMA:

- A category C or D vessel fishing on a combined monkfish and NE multispecies A DAS in the SFMA must fish with gillnets no smaller than 10-inches (25.4-cm) diamond mesh;
- Any monkfish-permitted vessel fishing in the SNE Dogfish Gillnet Exemption Area may retain dogfish and incidental limits of other species (excluding monkfish) allowed in the SNE Exemption Area; and
- Any monkfish-permitted vessel fishing in the SNE Monkfish and Skate Gillnet Exemption Area may retain monkfish and skate up to a specified limit and incidental limits of other

species (excluding dogfish) allowed in the SNE Regulated Mesh Area (RMA).

The proposed measure would modify a vessel's minimum gillnet mesh size requirements when fishing on a monkfish DAS using roundfish (also called stand-up) gillnets in the SFMA. It would also modify the minimum gillnet mesh size requirements in a smaller portion of the SFMA referred to as the Mid-Atlantic Exemption Area. Finally, this measure changes possession limit requirements in the SNE Dogfish Gillnet Exemption Area and dogfish in the SNE Monkfish and Skate Gillnet Exemption Area so that a vessel may retain both monkfish and dogfish. Please see Figure 1 for a display of these areas.

Figure 1. SNE Dogfish, Monkfish, and Skate Gillnet Exemption Area and Mid-Atlantic Exemption Area


75°W
70°W
45°N
40°N
35°N
ME
VT
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NY
MA
CT
PA
NJ
MD
VA
NC
Limit US EEZ
Monkfish Southern Fishery Management Area
Mid-Atlantic Exemption Area
SNE Dogfish Gillnet and SNE Monkfish & Skate Gillnet Exemption Areas

We are proposing to allow a Category C or D vessel fishing under both a NE multispecies and a monkfish DAS in the SFMA to use 6.5-inch (16.5-cm) roundfish gillnets. We are also proposing to allow any monkfish-permitted vessel fishing on a monkfish-only DAS in the Mid-Atlantic Exemption Area to use 5-inch (12.7-cm) roundfish gillnets in the Mid-Atlantic Exemption Area. Finally, we are proposing to allow a monkfish-permitted vessel fishing on a monkfish-only DAS in either the SNE Dogfish Gillnet Exemption Area or the SNE Monkfish and Skate Gillnet Exemption Area to retain both monkfish and dogfish on the same trip when declared into either area. This measure would also limit a vessel to using 50 roundfish gillnets in the SNE Dogfish and the Mid-Atlantic Exemption Areas. Table 3 summarizes the proposed measures (highlighted in bold) and also includes existing seasonal, gear, and DAS requirements.

TABLE 3—SUMMARY OF PROPOSED (BOLD) AND OTHER EXISTING REQUIREMENTS IN THE MONKFISH SFMA

	NE multispecies DAS anywhere in the SFMA	SNE Dogfish Gillnet exemption area	SNE Monkfish and Skate Gillnet exemption area	Mid-Atlantic exemption area
Minimum gillnet mesh	**6.5 inches (16.51 cm) for standup nets.**	6 inches (15.24 cm) for standup nets.	10 inches (25.4 cm) for all nets	**5 inches (12.7 cm) for standup nets.**
DAS	**NE multispecies and monkfish.**	Monkfish	Monkfish	**Monkfish.**
Season	Year-round	May 1–October 31	Year-round	**Year-round.**
Gear Limits	*All Trip gillnet vessels:* Unlimited. *Day gillnet vessel in the GB RMA:* 50 gillnets. *Day gillnet vessel in the SNE RMA:* 75 gillnets. *Day gillnet vessel in the MA RMA:* 75 gillnets.	*Category A/B:* 160 gillnets *Category C/D:* 150 gillnets *Roundfish gillnet limit:* 50 gillnets.	*Category A/B:* 160 gillnets *Category C/D:* 150 gillnets	***Category A/B:* 160 gillnets** ***Category C/D:* 150 gillnets** ***Roundfish gillnet limit:* 50 gillnets.**
Regulatory change to possess both Monkfish and Dogfish.	No	**Yes**	**Yes**	**Yes.**

A vessel taking advantage of these smaller minimum mesh sizer requirements must still comply with all other requirements of fishing in the SFMA or in the Exemption Areas. Existing monkfish possession limits for vessels issued a limited access monkfish permit and fishing in the SFMA would remain the same.

4. Corrections and Clarifications to Existing Regulations

This proposed rule would correct a number of inadvertent errors, omissions, and ambiguities in existing regulations in order to ensure consistency with, and accurately reflect the intent of, previous actions under the FMP, or to more effectively administer and enforce existing and proposed provisions pursuant to the authority provided to the Secretary of Commerce in section 305(d) of the Magnuson-Stevens Act. The following proposed measures are listed in the order in which they appear in the regulations.

In § 648.10, paragraphs (b)(3), (g)(1), (g)(3), and (g)(3)(ii)(A) would be revised to enhance readability and more clearly state the regulatory requirements.

In § 648.92, paragraph (b)(1)(i) would be revised to enhance readability and more clearly state the regulatory requirements. A reference to the DAS requirements in the SFMA and adjustment for gear conflicts would also be removed, as these references are unnecessary. The reference to DAS requirement in the SFMA in § 648.92(b)(1)(ii) is not needed because that referenced section further explains how the overall DAS allocation may be used. The reference to adjustment for gear conflicts in § 648.96(b)(3) states that the Councils may develop recommendations to address gear conflicts. This reference is unnecessary because those measures would be captured in the regulations and appropriately cross-referenced.

In § 648.94, paragraph (b)(3)(i) would be revised to enhance readability and more clearly state the regulatory requirements. A reference to Category F permits would also be deleted for clarity because it may cause confusion with regard to the possession limits for Category F permits. Possession limit requirements for Category F permits are more clearly outlined in § 648.95.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has made a preliminary determination that this proposed rule is consistent with the Monkfish and NE Multispecies FMPs, Framework 9, provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation, Department of Commerce, certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The Council prepared an analysis of the potential economic impacts of this action, which is included in the draft EA for this action (see **ADDRESSES** to obtain a copy of the EA) and supplemented by information contained in the preamble of this proposed rule. The SBA defines a small business in the commercial harvesting sector as a firm with receipts (gross revenues) of up to $5.5 million for shellfish businesses and $20.5 million for finfish businesses. There are 397 distinct ownership entities based on calendar year 2014 permits, the most complete full-year data available for the Council's analysis, that are directly regulated by this action. Of those 397 entities, 381 entities are categorized as small and 16 entities are categorized as large per the SBA guidelines.

This proposed rule is not expected to place small entities at a competitive disadvantage to large entities. All of the large entities impacted by the proposed action are primarily engaged in shellfish fishing. These large entities may not benefit to the same degree as small entities because the majority of small entities are primarily engaged in finfish fishing. The proposed rule would liberalize trip limits, increase operational flexibility, and relax minimum mesh size requirements, directly benefiting fishermen that are primarily engaged in finfish fishing. In terms of profitability, both small and large entities should benefit from increased operational flexibility from the proposed action, though these benefits are likely to be marginal.

There is no reason to believe small entities will be negatively affected in any way by the proposed measures identified in this rule's preamble. Overall, the net impact on profits from each proposed measure is expected to be slightly positive to neutral because these measures relieve restrictions. Therefore, this action is not expected to have a significant economic impact on a substantial number of small entities.

As a result, an initial regulatory flexibility analysis is not required and none has been prepared.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: June 20, 2016.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 648 is proposed to be amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 648.10, revise paragraphs (b)(3), (e)(5)(ii), (g)(1), and (g)(3) to read as follows:

§ 648.10 VMS and DAS requirements for vessel owners/operators.

* * * * *

(b) * * *

(3) A vessel issued a limited access monkfish, Occasional scallop, or Combination permit, whose owner elects to provide the notifications required by this section using VMS, unless otherwise authorized or required by the Regional Administrator under paragraph (d) of this section;

* * * * *

(e) * * *

(5) * * *

(ii) Notification that the vessel is not under the DAS program, the Access Area Program, the LAGC IFQ or NGOM scallop fishery, or any other fishery requiring the operation of VMS, must be received by NMFS prior to the vessel leaving port. A vessel may not change its status after the vessel leaves port or before it returns to port on any fishing trip, unless

(A) The vessel is a scallop vessel and is exempted, as specified in paragraph (f) of this section, or

(B) Unless the vessel is a NE multispecies sector vessel with a Monkfish Category C or D permit declaring a NE multispecies DAS while at sea, as specified in paragraph (g)(3)(ii) of this section.

* * * * *

(g) * * *

(1) The owner or authorized representative of a vessel that is required to or elects to use VMS, as specified in paragraph (b) of this section, must notify the Regional Administrator of the vessel's intended fishing activity by entering the appropriate VMS code prior to leaving port at the start of each fishing trip except:

(i) If notified by letter, pursuant to paragraph (e)(1)(iv) of this section, or

(ii) The vessel is a scallop vessel and is exempted, as specified in paragraph (f) of this section.

* * * * *

(3) A vessel operator cannot change any aspect of a vessel's VMS activity code outside of port, except as follows:

(i) An operator of a NE multispecies vessel is authorized to change the category of NE multispecies DAS used (*i.e.,* flip its DAS), as provided at § 648.85(b), or change the area declared to be fished so that the vessel may fish both inside and outside of the Eastern U.S./Canada Area on the same trip, as provided at § 648.85(a)(3)(ii)(A).

(ii) An operator of a vessel issued both a limited access NE multispecies permit and a limited access monkfish Category C or D permit is authorized to change the vessel's DAS declaration under the following circumstances:

(A) From a NE multispecies Category A DAS to a trip also using a monkfish DAS, as provided at § 648.92(b)(1)(iii)(A);

(B) From a NE multispecies sector non-DAS trip to a NE multispecies sector trip using a NE multispecies Category A DAS when fishing in the monkfish Northern Fishery Management Area (NFMA), if that vessel is participating in a sector; or

(C) From a trip under a monkfish-only DAS to a trip under both a monkfish and a NE multispecies Category A DAS when fishing in the monkfish NFMA, if that vessel is participating in a sector.

* * * * *

■ 3. In § 648.14, revise paragraph (m)(2)(i) to read as follows:

§ 648.14 Prohibitions.

* * * * *

(m)

(2) * * *

(i) Fish with or use nets with mesh size smaller than the minimum mesh size specified in § 648.91(c) while fishing under a monkfish DAS, except as authorized by § 648.91(c)(1)(iii).

* * * * *

■ 4. In § 648.80, revise paragraphs (b)(2)(iv), (b)(6)(i)(A), (b)(7)(i)(A)–(B), the introductory text to paragraph (c)(2)(v), and (c)(5) to read as follows:

§ 648.80 NE Multispecies regulated mesh areas and restrictions on gear and methods of fishing.

* * * * *

(b) * * *

(2) * * *

(iv) *Gillnet vessels.* For Day and Trip gillnet vessels, the minimum mesh size for any sink gillnet not stowed and not available for immediate use as defined in § 648.2, when fishing under a DAS in the NE multispecies DAS program or on a sector trip in the SNE Regulated Mesh Area, is 6.5 inches (16.5 cm) throughout the entire net. This restriction does not apply to nets or pieces of nets smaller than 3 ft (0.9 m) × 3 ft (0.9 m), (9 sq ft (0.81 sq m)), to vessels fishing with gillnet gear under a monkfish-only DAS in the SNE Dogfish Gillnet Exemption Area in accordance with the provisions specified under paragraph (b)(7)(i)(A) of this section; to vessels fishing with gillnet gear under a monkfish-only DAS in the Mid-Atlantic Exemption Area in accordance with the provisions specified under paragraph (c)(5)(ii) of this section; or to vessels that have not been issued a NE multispecies permit and that are fishing exclusively in state waters. Day gillnet vessels must also abide by the tagging requirements in paragraph (a)(3)(iv)(C) of this section.

* * * * *

(6) * * *

(i) * * *

(A) A vessel fishing under the SNE Monkfish and Skate Gillnet Exemption may only fish for, possess on board, or land monkfish as specified in § 648.94(b), spiny dogfish up to the amount specified in § 648.235, and other incidentally caught species up to the amounts specified in paragraph (b)(3) of this section.

* * * * *

(7) * * *

(i) * * *

(A) A vessel fishing under the SNE Dogfish Gillnet Exemption may only fish for, possess on board, or land dogfish and the bycatch species and amounts specified in paragraph (b)(3) of this section, unless fishing under a monkfish DAS. A vessel fishing under this exemption while on a monkfish-only DAS may also fish for, possess on board, and land monkfish up to the amount specified in § 648.94.

(B) All gillnets must have a minimum mesh size of 6-inch (15.2-cm) diamond mesh throughout the net. A vessel fishing under this exemption while on a monkfish-only DAS may not fish with, possess, haul, or deploy more than 50 roundfish gillnets, as defined in § 648.2.

* * * * *

(c) * * *

(2) * * *

(v) *Gillnet vessels.* For Day and Trip gillnet vessels, the minimum mesh size for any sink gillnet, not stowed and not available for immediate use as defined in § 648.2, when fishing under a DAS in the NE multispecies DAS program or on a sector trip in the MA Regulated Mesh Area, is 6.5 inches (16.5 cm) throughout the entire net. This restriction does not apply to nets or pieces of nets smaller than 3 ft (0.9 m) × 3 ft (0.9 m), (9 sq ft (0.81 sq m)), to vessels fishing with gillnet gear under a monkfish-only DAS in the Mid-Atlantic Exemption Area in accordance with the provisions specified under paragraph (c)(5)(ii) of this section, or to vessels that have not been issued a NE multispecies permit and that are fishing exclusively in state waters.

* * * * *

(5) *MA Exemption Area.* (i) The MA Exemption Area is that area that lies west of the SNE Exemption Area defined in paragraph (b)(10) of this section.

(ii) *Monkfish/Spiny Dogfish Exempted Gillnet Fishery.* A vessel fishing on a monkfish-only DAS may fish with, use, or possess gillnets in the MA Exemption Area with a mesh size smaller than the minimum size specified in paragraphs (b)(2)(iv) or (c)(2)(v) of this section, provided the vessel complies with the following requirements:

(A) *Number of nets.* Notwithstanding the provisions specified in paragraphs (c)(2)(v)(A) and (B) of this section and § 648.92(b)(8), a vessel fishing on a monkfish-only DAS within the MA Exemption Area may not fish with, possess, haul, or deploy more than 50 roundfish gillnets, as defined in § 648.2.

(B) *Minimum mesh size.* The minimum mesh size for any roundfish gillnet not stowed and available for immediate use by a vessel fishing on a monkfish-only DAS within the MA Exemption Area is 5 inches (12.7 cm) throughout the entire net.

(C) *Possession limits.* A vessel fishing on a monkfish-only DAS within the MA Exemption Area may fish for, possess on board, or land monkfish up to the amount specified in § 648.94, spiny dogfish up to the amount specified in § 648.235, and other incidentally caught species up to the amounts specified in paragraph (b)(3) of this section.

* * * * *

■ 5. In § 648.91, revise paragraph (c)(1)(iii) to read as follows:

§ 648.91 Monkfish regulated mesh areas and restrictions on gear and methods of fishing.

* * * * *

(c) * * *

(1) * * *

(iii) *Gillnets while on a monkfish DAS.* The minimum mesh size for any gillnets used by a vessel fishing under a monkfish DAS is 10-inch (25.4-cm) diamond mesh, unless:

(A) The owner or operator of a limited access NE multispecies vessel fishing under a NE multispecies category A DAS with gillnet gear in the NFMA changes the vessel's DAS declaration to a monkfish DAS through the vessel's VMS unit during the course of the trip in accordance with the provisions specified under § 648.92(b)(1)(iii);

(B) A vessel issued a Category C or D limited access monkfish permit is fishing under both a monkfish and NE multispecies Category A DAS in the SFMA using roundfish gillnets, as defined at § 648.2, with 6.5-inch (16.5-cm) diamond mesh;

(C) A vessel issued a limited access monkfish permit is fishing on a monkfish-only DAS in the Mid-Atlantic Exemption Area using roundfish gillnets with a minimum mesh size of 5 inches (12.7 cm) in accordance with the provisions specified under § 648.80(c)(5); or

(D) A vessel issued a limited access monkfish permit is fishing on a monkfish-only DAS in the Southern New England Dogfish Exemption Area using roundfish gillnets with a minimum mesh size of 6 inches (15.2 cm) in accordance with the provisions specified under § 648.80(b)(7).

* * * * *

■ 6. In § 648.92, revise paragraph (b)(1)(i) to read as follows:

§ 648.92 Effort-control program for monkfish limited access vessels.

* * * * *

(b) * * *

(1) * * *

(i) *General provision.* Each vessel issued a limited access monkfish permit shall be allocated 46 monkfish DAS each fishing year, which must be used in accordance with the provisions of this paragraph (b), unless the permit is enrolled in the Offshore Fishery Program in the SFMA, as specified in paragraph (b)(1)(iv) of this section. The annual allocation of monkfish DAS to each limited access monkfish permit shall be reduced by the amount calculated in paragraph (b)(1)(v) of this section for the research DAS set-aside. Unless otherwise specified in paragraph (b)(2) of this section or under this subpart F, a vessel issued a limited access NE multispecies or limited access sea scallop permit that is also issued a limited access monkfish permit must use a NE multispecies or sea scallop DAS concurrently with each monkfish DAS utilized.

* * * * *

■ 7. In § 648.94, revise paragraphs (b)(1) and (b)(3)(i) to read as follows:

§ 648.94 Monkfish possession and landing restrictions.

* * * * *

(b) * * *

(1) *Vessels fishing under the monkfish DAS program in the NFMA—*

(i) *Category A vessels.* A limited access monkfish Category A vessel that fishes exclusively in the NFMA under a monkfish DAS may land up to 1,250 lb (567 kg) tail weight or 3,638 lb (1,650 kg) whole weight of monkfish per DAS (or any prorated combination of tail weight and whole weight based on the conversion factor for tail weight to whole weight of 2.91). For every 1 lb (0.45 kg) of tail only weight landed, the vessel may land up to 1.91 lb (0.87 kg) of monkfish heads only, as described in paragraph (a) of this section.

(ii) *Category B vessels.* A limited access monkfish Category B vessel that fishes exclusively in the NFMA under a monkfish DAS may land up to 600 lb (272 kg) tail weight or 1,746 lb (792 kg) whole weight of monkfish per DAS (or any prorated combination of tail weight and whole weight based on the conversion factor for tail weight to whole weight of 2.91). For every 1 lb (0.45 kg) of tail only weight landed, the vessel may land up to 1.91 lb (0.87 kg) of monkfish heads only, as described in paragraph (a) of this section.

(iii) *Category C vessels.* A limited access monkfish Category C vessel that fishes exclusively in the NFMA under a monkfish-only DAS may land up to 1,250 lb (567 kg) tail weight or 3,638 lb (1,650 kg) whole weight of monkfish per DAS (or any prorated combination of tail weight and whole weight based on the conversion factor for tail weight to whole weight of 2.91). A limited access monkfish Category C vessel that fishes exclusively in the NFMA under both a monkfish and NE multispecies DAS may possess and land an unlimited amount of monkfish. For every 1 lb (0.45 kg) of tail only weight landed, the vessel may land up to 1.91 lb (0.87 kg) of monkfish heads only, as described in paragraph (a) of this section.

(iv) *Category D vessels.* A limited access monkfish Category D vessel that fishes exclusively in the NFMA under a monkfish-only DAS may land up to 600 lb (272 kg) tail weight or 1,746 lb (792 kg) whole weight of monkfish per DAS (or any prorated combination of tail weight and whole weight based on the conversion factor for tail weight to whole weight of 2.91). A limited access monkfish Category D vessel that fishes exclusively in the NFMA under both a monkfish and NE multispecies DAS may possess and land an unlimited amount of monkfish. For every 1 lb (0.45 kg) of tail only weight landed, the vessel may land up to 1.91 lb (0.87 kg) of monkfish heads only, as described in paragraph (a) of this section.

* * * * *

(3) * * *

(i) *NFMA.* Unless otherwise specified in paragraph (b)(1) of this section, a vessel issued a limited access monkfish Category C permit that fishes under a NE multispecies DAS, and not a monkfish DAS, exclusively in the NFMA may land up to 600 lb (272 kg) tail weight or 1,746 lb (792 kg) whole weight of monkfish per DAS (or any prorated combination of tail weight and whole weight based on the conversion factor for tail weight to whole weight of 2.91). A vessel issued a limited access monkfish Category D permit that fishes under a NE multispecies DAS, and not a monkfish DAS, exclusively in the NFMA may land up to 500 lb (227 kg) tail weight or 1,455 lb (660 kg) whole weight of monkfish per DAS (or any prorated combination of tail weight and whole weight based on the conversion factor for tail weight to whole weight of 2.91). A vessel issued a limited access monkfish Category C, D, or F permit participating in the NE Multispecies Regular B DAS program, as specified under § 648.85(b)(6), is also subject to the incidental landing limit specified in paragraph (c)(1)(i) of this section on such trips.

* * * * *

[FR Doc. 2016–14888 Filed 6–22–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 160617540–6540–01]

RIN 0648–XE695

Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Annual Specifications

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule.

SUMMARY: NMFS proposes to implement annual management measures and harvest specifications to establish the allowable catch levels (*i.e.* annual catch limit (ACL)/harvest guideline (HG)) for Pacific mackerel in the U.S. exclusive economic zone (EEZ) off the West Coast for the fishing season of July 1, 2016, through June 30, 2017. This rule is proposed pursuant to the Coastal

Pelagic Species (CPS) Fishery Management Plan (FMP). The proposed 2016–2017 HG for Pacific mackerel is 21,161 metric tons (mt). This is the total commercial fishing target level. NMFS also proposes an annual catch target (ACT), of 20,161 mt. If the fishery attains the ACT, the directed fishery will close, reserving the difference between the HG (21,161 mt) and ACT as a 1,000 mt set-aside for incidental landings in other CPS fisheries and other sources of mortality. This proposed rule is intended to conserve and manage the Pacific mackerel stock off the U.S. West Coast.

DATES: Comments must be received by July 25, 2016.

ADDRESSES: You may submit comments on this document identified by NOAA–NMFS–2015–0048, by any of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2015-0048,* click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to William W. Stelle, Jr., Regional Administrator, West Coast Region, NMFS, 7600 Sand Point Way NE., Seattle, WA 98115–0070; Attn: Joshua Lindsay.

Instructions: Comments must be submitted by one of the above methods to ensure that the comments are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).

Copies of the report "Pacific Mackerel (*Scomber japonicus*) Stock Assessment for USA Management in the 2015–2016 Fishing Year" may be obtained from the West Coast Region (see **ADDRESSES**).

FOR FURTHER INFORMATION CONTACT: Joshua Lindsay, West Coast Region, NMFS, (562) 980–4034, *Joshua.Lindsay@noaa.gov.*

SUPPLEMENTARY INFORMATION: During public meetings each year, the estimated biomass for Pacific mackerel is presented to the Pacific Fishery Management Council's (Council) CPS Management Team (Team), the Council's CPS Advisory Subpanel (Subpanel) and the Council's Scientific and Statistical Committee (SSC), and the biomass and the status of the fishery are reviewed and discussed. The biomass estimate is then presented to the Council along with the recommended overfishing limit (OFL) and acceptable biological catch (ABC) calculations from the SSC, along with the calculated ACL, HG, and ACT recommendations, and comments from the Team and Subpanel. Following review by the Council and after reviewing public comment, the Council adopts a biomass estimate and makes its catch level recommendations to NMFS. Under the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1801 *et seq.,* NMFS manages the Pacific mackerel fishery in the U.S. EEZ off the Pacific coast (California, Oregon, and Washington) in accordance with the FMP. Annual Specifications published in the **Federal Register** establish the allowable harvest levels (*i.e.* OFL/ACL/HG) for each Pacific mackerel fishing year. The purpose of this proposed rule is to implement the 2016–2017 ACL, HG, ACT and other annual catch reference points, including an OFL and an ABC that take into consideration uncertainty surrounding the current estimate of biomass for Pacific mackerel in the U.S. EEZ off the Pacific coast.

The CPS FMP and its implementing regulations require NMFS to set these annual catch levels for the Pacific mackerel fishery based on the annual specification framework and control rules in the FMP. These control rules include the HG control rule, which in conjunction with the OFL and ABC rules in the FMP, are used to manage harvest levels for Pacific mackerel, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1801 *et seq.* According to the FMP, the quota for the principal commercial fishery is determined using the FMP-specified HG formula. The HG is based, in large part, on the current estimate of stock biomass. The annual biomass estimates are an explicit part of the various harvest control rules for Pacific mackerel, and as the estimated biomass decreases or increases from one year to the next, the resulting allowable catch levels similarly trend. The harvest control rule in the CPS FMP is HG = [(Biomass-Cutoff) * Fraction * Distribution] with the parameters described as follows:

1. *Biomass.* The estimated stock biomass of Pacific mackerel. For the 2016–2017 management season this is 118,968 mt.
2. *Cutoff.* This is the biomass level below which no commercial fishery is allowed. The FMP established this level at 18,200 mt.
3. *Fraction.* The harvest fraction is the percentage of the biomass above 18,200 mt that may be harvested.
4. *Distribution.* The average portion of the Pacific mackerel biomass estimated in the U.S. EEZ off the Pacific coast is 70 percent and is based on the average historical larval distribution obtained from scientific cruises and the distribution of the resource according to the logbooks of aerial fish-spotters.

At the June 2015 Council meeting, the Council adopted a new full stock assessment for Pacific mackerel completed by NMFS Southwest Fisheries Science Center and along with the Council's SSC, approved the resulting Pacific mackerel biomass estimate of 118,968 mt as the best available science for use in the 2016–2017 fishing year. Based on recommendations from its SSC and other advisory bodies, the Council recommended and NMFS is proposing, an OFL of 24,983 mt, an ABC and ACL of 22,822 mt, an HG of 21,161 mt, and an ACT of 20,161 mt for the fishing year of July 1, 2016, to June 30, 2017.

Under this proposed action, upon attainment of the ACT, the directed fishing would close, reserving the difference between the HG and ACT (1,000 mt) as a set aside for incidental landings in other CPS fisheries and other sources of mortality. For the remainder of the fishing year, incidental landings would also be constrained to a 45 percent incidental catch allowance when Pacific mackerel are landed with other CPS (in other words, no more than 45 percent by weight of the CPS landed per trip may be Pacific mackerel), except that up to 3 mt of Pacific mackerel could be landed incidentally without landing any other CPS. Upon attainment of the HG (21,161 mt), no retention of Pacific mackerel would be allowed in CPS fisheries. In previous years, the incidental set-aside established in the mackerel fishery has been, in part, to ensure that if the directed quota for mackerel was reached that the operation of the Pacific sardine fishery was not overly restricted. There is no directed Pacific sardine fishery for the 2016–2017 season; therefore, the need for a high incidental set-aside is reduced. The purpose of the incidental set-aside and the allowance of an incidental fishery is to allow for restricted incidental landings of Pacific mackerel in other fisheries, particularly other CPS fisheries, when the directed fishery is closed to reduce potential discard of Pacific mackerel and allow for continued prosecution of other important CPS fisheries.

The NMFS West Coast Regional Administrator would publish a notice in the **Federal Register** announcing the date of any closure to either directed or incidental fishing. Additionally, to ensure the regulated community is informed of any closure, NMFS would also make announcements through other means available, including fax, email, and mail to fishermen, processors, and state fishery management agencies.

Detailed information on the fishery and the stock assessment are found in the report "Pacific Mackerel (*Scomber japonicus*) Stock Assessment for USA Management in the 2015–16 Fishing Year" (see **ADDRESSES**).

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Fishery Conservation and Management Act, the Assistant Administrator, NMFS, has determined that this proposed rule is consistent with the CPS FMP, other provisions of the Magnuson-Stevens Fishery Conservation and Management Act, and other applicable law, subject to further consideration after public comment.

These proposed specifications are exempt from review under Executive Order 12866 because they contain no implementing regulations.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities, for the following reasons:

The U.S. Small Business Administration (SBA) defines small businesses engaged in finfish fishing as those vessels with annual revenues of or below $20.5 million. The small entities that would be affected by the proposed action are the vessels that compose the West Coast CPS finfish fleet and are all considered small businesses under these size standards.

The small entities that would be affected by the proposed action are those vessels that harvest Pacific mackerel as part of the West Coast CPS purse seine fleet. The CPS FMP and its implementing regulations requires NMFS to set an OFL, ABC, ACL, HG, or ACT for the Pacific mackerel fishery based on the harvest control rules in the FMP. These specific harvest control rules are applied to the current stock biomass estimate to derive these catch specifications, which are used to manage the commercial take of Pacific mackerel. A component of these control rules is that as the estimated biomass decreases or increases from one year to the next, so do the applicable quotas. For the 2016–2017 Pacific mackerel fishing season NMFS is proposing an OFL of 24,983 metric tons (mt), an ABC and ACL of 22,822 mt, an HG of 21,161 mt, and an ACT, which is the directed fishing harvest target, of 20,161 mt. These catch specifications are based on a biomass estimate of 118,968 mt.

Pacific mackerel harvest is one component of CPS fisheries off the U.S. West Coast, which primarily includes the fisheries for Pacific sardine, northern anchovy, and market squid. Pacific mackerel are principally caught off southern California within the limited entry portion (south of 39 degrees N. latitude; Point Arena, California) of the fishery. Currently there are 56 vessels permitted in the Federal CPS limited entry fishery off California of which about 25 to 39 vessels have been annually engaged in harvesting Pacific mackerel in recent years (2009–2015). For those vessels that caught Pacific mackerel during that time, the average annual per vessel revenue has been about $1.25 million. The individual vessel revenue for these vessels is well below the SBA's threshold level of $20.5 million; therefore, all of these vessels are considered small businesses under the RFA. Because each affected vessel is a small business, this proposed rule has an equal or similar effect on all of these small entities, and therefore will impact a substantial number of these small entities in the same manner.

NMFS used the ex-vessel revenue information for a profitability analysis, as the cost data for the harvesting operations of CPS finfish vessels was limited or unavailable. For the 2015–2016 fishing year, the maximum fishing level was 25,291 mt and was divided into a directed fishing harvest target (ACT) of 20,469 mt and an incidental set-aside of 5,000 mt. As of April 29, 2016 approximately 3,880 mt of Pacific mackerel was harvested in the 2015–2016 fishing season with an estimated ex-vessel value of approximately $931,200.

The maximum fishing level for the 2016–2017 Pacific mackerel fishing season is 21,161 mt, with an ACT of 20,161 mt and an incidental set-aside of 1,000 mt. This proposed ACT is nearly equivalent to the ACT established for the previous year, thus it is highly unlikely that the ACT proposed in this rule will limit the potential profitability to the fleet from catching Pacific mackerel compared to last season or recent catch levels, as shown below. The annual average U.S. Pacific mackerel harvest in recent years (2010–2015) has been about 5,000 mt. In this period, the landings have not exceeded 11,800 mt. Additionally, annual average landings during the last decade (2005–2015) have not been restricted by the applicable quota. Accordingly, vessel income from fishing is not expected to be altered as a result of this rule as it compares to recent catches in the fishery, including under the previous season's regulations.

Based on the disproportionality and profitability analysis above, the proposed action, if adopted, will not have a significant economic impact on a substantial number of small entities. As a result, an Initial Regulatory Flexibility Analysis is not required, and none has been prepared.

This action does not contain a collection-of-information requirement for purposes of the Paperwork Reduction Act.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: June 17, 2016.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2016–14839 Filed 6–22–16; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 81, No. 121
Thursday, June 23, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

Meetings

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Notice of meetings.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (Access Board) plans to hold its regular committee and Board meetings in Washington, DC, Monday through Wednesday, July 11–13, 2016 at the times and location listed below.

DATES: The schedule of events is as follows:

Monday, July 11, 2016

2:30 p.m.–3:30 p.m. Technical Programs Committee
3:30 p.m.–4:30 p.m. Ad Hoc Committee on Design Guidance

Tuesday, July 12, 2016

9:30 a.m.–Noon Ad Hoc Committee on Frontier Issues
1:30 p.m.–2:00 p.m. Budget
2:00 p.m.–3:00 p.m. Planning and Evaluation
3:00 p.m.–4:30 p.m. Ad Hoc Committee on Information and Communications Technologies: CLOSED

Wednesday, July 13, 2016

1:30 p.m.–3:00 p.m. Board Meeting

ADDRESSES: Meetings will be held at the Access Board Conference Room, 1331 F Street NW., Suite 800, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: For further information regarding the meetings, please contact David Capozzi, Executive Director, (202) 272–0010 (voice); (202) 272–0054 (TTY).

SUPPLEMENTARY INFORMATION: At the Board meeting scheduled on the afternoon of Wednesday, July 13, 2016, the Access Board will consider the following agenda items:

- Approval of the draft March 9, 2016 meeting minutes (vote)
- Ad Hoc Committee Reports: Design Guidance; Frontier Issues; and Information and Communication Technology
- Technical Programs Committee (vote)
- Budget Committee
- Planning and Evaluation Committee
- Election Assistance Commission Report
- Executive Director's Report
- Public Comment (final 15 minutes of the meeting)

Members of the public can provide comments either in-person or over the telephone during the final 15 minutes of the Board meeting on Wednesday, July 13, 2016. Any individual interested in providing comment is asked to pre-register by sending an email to *bunales@access-board.gov* with the subject line "Access Board meeting—Public Comment" with your name, organization, state, and topic of comment included in the body of your email. All emails to register for public comment must be received by Wednesday, July 6, 2016. Commenters will be called on in the order by which they pre-registered. Due to time constraints, each commenter is limited to two minutes. Commenters on the telephone will be in a listen-only capacity until they are called on. Use the following call-in number: (877) 701–1628; passcode: 9667 7809 and dial in 5 minutes before the meeting begins at 1:30 p.m.

All meetings are accessible to persons with disabilities. An assistive listening system, Communication Access Realtime Translation (CART), and sign language interpreters will be available at the Board meeting and committee meetings. Persons attending Board meetings are requested to refrain from using perfume, cologne, and other fragrances for the comfort of other participants (see *www.access-board.gov/the-board/policies/fragrance-free-environment* for more information).You may view the Wednesday, July 13, 2016 meeting through a live webcast from 1:30 p.m. to 3:00 p.m. at: *www.access-board.gov/webcast.*

David M. Capozzi,
Executive Director.

[FR Doc. 2016–14889 Filed 6–22–16; 8:45 am]

BILLING CODE 8150–01–P

COMMISSION ON CIVIL RIGHTS

Public Meeting of the Indiana Advisory Committee To Discuss Findings and Recommendations Regarding Civil Rights and the School to Prison Pipeline in Indiana

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Indiana Advisory Committee (Committee) will hold a meeting on Wednesday, July 20, 2016, from 10:00 a.m.–11:00 a.m. EDT. The Committee will discuss findings and recommendations regarding school discipline policies and practices which may facilitate disparities in juvenile justice involvement and youth incarceration rates on the basis of race, color, disability, or sex, in what has become known as the "School to Prison Pipeline," in preparation to issue a report to the Commission on the topic. This meeting is open to the public via the following toll free call in number 888–471–3843 conference ID 4507232. Any interested member of the public may call this number and listen to the meeting. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are invited to make statements during the designated open comment period. In addition, members of the public may submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the

Regional Programs Unit, U.S. Commission on Civil Rights, 55 W. Monroe St., Suite 410, Chicago, IL 60615. They may also be faxed to the Commission at (312) 353–8324, or emailed to Carolyn Allen at *callen@usccr.gov*. Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

Records and documents discussed during the meeting will be available for public viewing prior to and following the meeting at *https://database.faca.gov/committee/meetings.aspx?cid=247* and following the links for "Meeting Details" and then "Documents." Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov*, or may contact the Regional Programs Unit at the above email or street address.

Agenda

1. Welcome and Roll Call
2. Findings and Recommendations: "Civil Rights and the School to Prison Pipeline in Indiana"
3. Open Comment
4. Adjournment

DATES: The meeting will be held on Wednesday July 20, 2016, from 10:00 a.m.–11:00 a.m. EDT.

Public Call Information:

Dial: 888–471–3843
Conference ID: 4507232

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at 312–353–8311 or *mwojnaroski@usccr.gov*

Dated: June 20, 2016.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2016–14857 Filed 6–22–16; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the North Carolina Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the North Carolina Advisory Committee will hold a meeting on Friday, June 29, 2016, at 12 p.m. EST for the purpose of discussing and voting on potential summary memorandum project and to discuss a draft report on environmental justice issues in the state.

DATES: The meeting will be held on Wednesday, June 29, 2016 at 12 p.m. EST.

SUPPLEMENTARY INFORMATION: Members of the public can listen to the discussion. This meeting is available to the public through the following toll-free call-in number: 888–455–2296, conference ID: 6491793. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are invited to make statements to the Committee during the scheduled open comment period. In addition, members of the public may submit written comments; the comments must be received in the regional office by June 25, 2016. Written comments may be mailed to the Southern Regional Office, U.S. Commission on Civil Rights, 61 Forsyth Street, Suite 16T126, Atlanta, GA 30303. They may also be faxed to the Commission at (404) 562–7005, or emailed to Regional Director, Jeffrey Hinton at *jhinton@usccr.gov*. Persons who desire additional information may contact the Southern Regional Office at (404) 562–7000.

Records generated from this meeting may be inspected and reproduced at the Southern Regional Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, North Carolina Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov*, or may contact the Southern Regional Office at the above email or street address.

Agenda

- Welcome/Member participation roll call—Jeff Hinton, Regional Director; Matty Lazo-Chadderton, Chairman—NC SAC
- North Carolina Advisory Committee discussion and vote on potential summary memorandum project (Coal Ash) to the U.S. Commission on Civil Rights—Matty Lazo-Chadderton, Chair/Staff/Advisory Committee
- Public Participation
- Adjournment

Public Call Information

Toll-free call-in number: 888–455–2296,

Conference ID: 6491793.

Dated: June 13, 2016.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2016–14268 Filed 6–22–16; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Montana Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a planning meeting of the Montana Advisory Committee to the Commission will convene at 10:00 a.m. (MDT) on Wednesday, July 20, 2016, via teleconference. The purpose of the planning meeting is for the Advisory Committee to review progress of planning to conduct a community forum on Border Town Discrimination Against Native Americans in Billings in late August 2016.

Members of the public may listen to the discussion by dialing the following Conference Call Toll-Free Number: 1–888–503–8175; Conference ID: 5890742. Please be advised that before being placed into the conference call, the operator will ask callers to provide their names, their organizational affiliations (if any), and an email address (if available) prior to placing callers into the conference room. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free phone number.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service (FRS) at 1–800–977–8339 and provide the FRS operator with the Conference Call Toll-Free Number: 1–888–503–8175, Conference ID: 5890742. Members of the public are invited to submit written comments; the comments must be received in the regional office by

Monday, August 22, 2016. Written comments may be mailed to the Rocky Mountain Regional Office, U.S. Commission on Civil Rights, 1961 Stout Street, Suite 13–201, Denver, CO 80294, faxed to (303) 866–1050, or emailed to Evelyn Bohor at *ebohor@usccr.gov*. Persons who desire additional information may contact the Rocky Mountain Regional Office at (303) 866–1040.

Records and documents discussed during the meeting will be available for public viewing as they become available at *https://database.faca.gov/committee/meetings.aspx?cid=259* and clicking on the "Meeting Details" and "Documents" links. Records generated from this meeting may also be inspected and reproduced at the Rocky Mountain Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *www.usccr.gov*, or to contact the Rocky Mountain Regional Office at the above phone number, email or street address.

Agenda

Welcome and Roll Call
  Norma Bixby, Chair, Montana State Advisory Committee
  Malee V. Craft, Regional Director and Designated Federal Official (DFO)
Discussion of Progress Made Towards Community Forum on Border Town Discrimination
  Montana Advisory Committee

DATES: Wednesday, July 20, 2016, at 10:00 a.m. (MDT)

ADDRESSES: To be held via teleconference:

Conference Call Toll-Free Number: 1–888–503–8175, Conference ID: 5890742.

TDD: Dial Federal Relay Service 1–800–977–8339 and give the operator the above conference call number and conference ID.

FOR FURTHER INFORMATION CONTACT: Malee V. Craft, Regional Director, *mcraft@usccr.gov*, 303–866–1040

Dated: June 20, 2016.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2016–14858 Filed 6–22–16; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: U.S. Census Bureau.

Title: Quarterly Summary of State and Local Government Tax Revenues.

OMB Control Number: 0607–0112.

Form Number(s): F–71, F–72, F–73.

Type of Request: Revision of a currently approved collection.

Number of Respondents: 7,351.

Average Hours per Response: F–71—5 minutes; F–72—30 minutes; F–73—20 minutes.

Burden Hours: 7,978.

Needs and Uses: State and local government tax collections, amounting to nearly $1.4 trillion annually, constitute approximately 43 percent of all governmental revenues. Quarterly measurement of, and reporting on, these fund flows provides valuable insight into trends in the national economy and that of individual states. Information collected on the type and quantity of taxes collected gives comparative data on how the various levels of government fund their public sector obligations.

The Census Bureau conducts the Quarterly Summary of State & Local Government Tax Revenues (Q-Tax Survey) to provide quarterly estimates of state and local government tax revenue at a national level, as well as detailed tax revenue data for individual states. It serves as a timely source of tax data for many data users and policy makers and is the most current information available on a nationwide basis for government tax collections. There are three components to the Q-Tax Survey. The first component is the Quarterly Survey of Property Tax Collections (F–71), which collects property tax data from local governments. The second component is the Quarterly Survey of State Tax Collections (F–72), which collects data comprised of 25 different tax categories for all 50 states. The third component is the Quarterly Survey of Selected Non-Property Taxes (F–73), which collects local tax revenue data for three taxes: sales and gross receipts taxes, individual income taxes, and corporation net income taxes.

The Census Bureau requests a change from paper forms to all-electronic data collection methods for the Q-Tax Survey. The Quarterly Survey of Property Tax Collections (F–71) and Quarterly Survey of Selected Non-Property Taxes (F–73) components will be collected electronically via Centurion, the Census Bureau's primary online reporting system. For the Quarterly Survey of State Tax Collections (F–72) component, respondents will be emailed a spreadsheet to fill out and return electronically.

The Census Bureau conducts the three components of the Q-Tax Survey to collect state and local government tax data for this data series established in 1962. Tax collection data are used to measure economic activity for the Nation as a whole, as well as for comparison among the states. These data are also used in comparing the mix of taxes employed by individual states and in determining the revenue raising capacity of different types of taxes in different states.

Key users of these data include the Bureau of Economic Analysis (BEA), the Federal Reserve Board (FRB), and the Department of Housing and Urban Development (HUD) who rely on these data to provide the most current information on the financial status of state and local governments. These data are included in the quarterly estimates of the National Income and Product Accounts developed by BEA. HUD has used the property tax data as one of nine cost indicators for developing Section 8 rent adjustments. Legislators, policy makers, administrators, analysts, economists, and researchers use these data to monitor trends in public sector revenues. Journalists, teachers, and students use these data as well for their research purposes.

Affected Public: State, local, or Tribal government.

Frequency: Quarterly.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C., Sections 161 and 182.

This information collection request may be viewed at *www.reginfo.gov*. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: June 17, 2016.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2016–14838 Filed 6–22–16; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, Department of Commerce.

ACTION: Notice and Opportunity for Public Comment.

Pursuant to Section 251 of the Trade Act 1974, as amended (19 U.S.C. 2341 *et seq.*), the Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of these firms contributed importantly to the total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[6/11/2016 through 6/17/2016]

Firm name	Firm address	Date accepted for investigation	Product(s)
Marlen Textiles, Inc	500 Orchard Street, New Haven, MO 63068–1108.	6/16/2016	The firm is a manufacturer of economy fabrics used to make boat covers, tarps, furniture covers, awnings, tents and other products.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance for Firms Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Dated: June 17, 2016.

Miriam Kearse,

Lead Program Analyst.

[FR Doc. 2016–14855 Filed 6–22–16; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–88–2016]

Foreign-Trade Zone 18—San Jose, California; Application for Subzone Expansion; Subzone 18G; Tesla Motors, Inc.; Palo Alto and Fremont, California

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the City of San Jose, California, grantee of FTZ 18, requesting to expand Subzone 18G on behalf of Tesla Motors, Inc., located in Palo Alto and Fremont, California. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on June 15, 2016.

Subzone 18G was approved on September 20, 2012 (77 FR 60672–60673, October 4, 2012) and currently consists of two sites: *Site 1* (25.2 acres)—3500 Deer Creek Road, Palo Alto; and, *Site 2* (210 acres)—45550 Fremont Boulevard, Fremont. The applicant is now requesting authority to expand the subzone to include an additional 24.5 acres located adjacent to *Site 2*. No additional production authority is being requested at this time. The expanded subzone would be subject to the existing activation limit of FTZ 18.

In accordance with the FTZ Board's regulations, Christopher Kemp of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is August 2, 2016. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to August 17, 2016.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the "Reading Room" section of the FTZ Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Christopher Kemp at *christopher.kemp@trade.gov* or (202) 482–0862.

Dated: June 15, 2016.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2016–14809 Filed 6–22–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–843]

Prestressed Concrete Steel Rail Tie Wire From Mexico: Final Results of Antidumping Duty Administrative Review; 2013–2015

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On March 9, 2016, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty (AD) order on prestressed concrete steel rail tie wire (PC tie wire) from Mexico.[1] The period of review (POR) is December 12, 2013, through May 31, 2015. The review covers one producer/exporter of the subject merchandise, Aceros Camesa, S.A. de C.V. (Camesa). We gave interested parties an opportunity to comment on the *Preliminary Results.* After considering the comments received, we made no changes to our preliminary margin calculations, and we

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[1] *See Prestressed Concrete Steel Rail Tie Wire From Mexico: Preliminary Results of the Antidumping Duty Administrative Review; 2013–2105,* 81 FR 12466 (March 9, 2016) (*Preliminary Results*).

continue to find that Camesa made sales of subject merchandise to the United States at prices below normal value. Camesa's final dumping margin is listed below in the section entitled "Final Results of the Review."

DATES: *Effective Date:* June 23, 2016.

FOR FURTHER INFORMATION CONTACT: Rebecca Trainor or Aqmar Rahman, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–4007 and (202) 482–0768, respectively.

SUPPLEMENTARY INFORMATION:

Background

For a complete description of the events following the publication of the *Preliminary Results, see* the Issues and Decision Memorandum.[2] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's AD and Countervailing Duty (CVD) Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

The Department conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The product covered by this order is prestressed concrete steel rail tie wire. This product is classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheading 7217.10.8045, but may also be classified under subheadings 7217.10.7000, 7217.10.8025, 7217.10.8030, 7217.10.8090, 7217.10.9000, 7229.90.1000, 7229.90.5016, 7229.90.5031, 7229.90.5051, 7229.90.9000, and 7312.10.3012. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.[3]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are addressed in the Issues and Decision Memorandum. A list of the issues which parties raised and to which we respond in the Issues and Decision Memorandum is attached to this notice as Appendix I.

Final Results of the Review

As a result of this review, the Department determines that a weighted-average dumping margin of 6.33 percent exists for Camesa for the period December 12, 2013, through May 31, 2015.

Assessment Rates

The Department determines, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[4] We calculated an importer-specific *ad valorem* duty assessment rate based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of the examined sales to that importer. We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review if the importer-specific assessment rate is above *de minimis.*

We intend to issue instructions to CBP 41 days after the date of publication of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Camesa will be the rate established in these final results; (2) for previously reviewed or investigated companies not participating in this review, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a previous review, or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 9.99 percent, the all-others rate made effective by the LTFV investigation. These deposit requirements shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This administrative review and notice are published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221.

Dated: June 15, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Margin Calculations
IV. Scope of the Order
V. Discussion of the Issues
  A. Clerical Error in the Draft Liquidation Instructions
  B. Camesa's General and Administrative (G&A) Expense Offset
VI. Recommendation

[FR Doc. 2016–14913 Filed 6–22–16; 8:45 am]

BILLING CODE 3510–DS–P

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[2] *See* memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, "Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review of Prestressed Concrete Steel Rail Tie Wire from Mexico; 2013–2015," dated concurrently with and adopted by this notice (Issues and Decision Memorandum).

[3] A full description of the scope of the order is contained in the Issues and Decision Memorandum.

[4] *See* 19 CFR 351.212(b)(1).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE603

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Gustavus Ferry Terminal Improvements Project

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; proposed incidental harassment authorization; request for comments.

SUMMARY: NMFS has received a request from the Alaska Department of Transportation and Public Facilities (ADOT&PF) for authorization to take marine mammals incidental to reconstructing the existing Gustavus Ferry Terminal located in Gustavus, Alaska. The ADOT&PF requests that the incidental harassment authorization (IHA) be valid for one year from September 1, 2017 through August 31, 2018. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an authorization to the ADOT&PF to incidentally take, by harassment, small numbers of marine mammals for its ferry terminal improvements project in Gustavus, AK.

DATES: Comments and information must be received no later than July 25, 2016.

ADDRESSES: Comments on the application should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Physical comments should be sent to 1315 East-West Highway, Silver Spring, MD 20910, and electronic comments should be sent to *ITP.Pauline@noaa.gov*.

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments received electronically, including all attachments, must not exceed a 25-megabyte file size. Attachments to electronic comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted to the Internet at *http://www.nmfs.noaa.gov/pr/permits/incidental/construction.htm* without change. All personal identifying information (*e.g.*, name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Robert Pauline, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Availability: An electronic copy of ADOT&PF's application and supporting documents, as well as a list of the references cited in this document, may be obtained by visiting the Internet at: *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm*. In case of problems accessing these documents, please call the contact listed above (see **FOR FURTHER INFORMATION CONTACT**).

National Environmental Policy Act

NMFS is preparing an Environmental Assessment (EA) in accordance with National Environmental Policy Act (NEPA) and the regulations published by the Council on Environmental Quality and will consider comments submitted in response to this notice as part of that process. The draft EA will be posted at the foregoing Web site once it is finalized.

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined "negligible impact" in 50 CFR 216.103 as "an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival."

Except with respect to certain activities not pertinent here, the MMPA defines "harassment" as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

Summary of Request

On July 31, 2015, NMFS received an application from the ADOT&PF for the taking of marine mammals incidental to reconstructing the existing ferry terminal at Gustavus, Alaska, referred to as the Gustavus Ferry Terminal. On April 15, 2016, NMFS received a revised application. NMFS determined that the application was adequate and complete on April 20, 2016. ADOT&PF proposes to conduct in-water work that may incidentally harass marine mammals (*i.e.*, pile driving and removal). This IHA would be valid from September 1, 2017 through August 31, 2018.

Proposed activities included as part of the Gustavus Ferry Improvements project with potential to affect marine mammals include vibratory pile driving and pile removal, as well as impact hammer pile driving.

Species with the expected potential to be present during the project timeframe include harbor seal (*Phoca viutlina*), Steller sea lion (*Eumetopias jubatus*), harbor porpoise (*Phocoena phocoena*), Dall's porpoise (*Phocoenoides dalli*), killer whale (*Orcinus orca*), humpback whale (*Megaptera novaeangliae*), and minke whale (*Balaenoptera acutorostra*).

Description of the Specified Activity

Overview

The purpose of the project is to improve the vehicle transfer span and dock such that damage during heavy storms is prevented, and to improve the safety of vehicle and pedestrian transfer operations. ADOT&PF requested an IHA for work that includes removal of the existing steel bridge float and restraint structure and replacing it with two steel/concrete bridge lift towers capable of elevating the relocated steel transfer bridge above the water when not in use. Each tower would be supported by four 30-inch steel piles.

Dates and Duration

Pile installation and extraction associated with the Gustavus Ferry Terminal project will begin no sooner than September 1, 2017 and will be completed no later than August 31, 2018 (one year following IHA issuance). Project activities are proposed to occur during two time periods. The first period will occur in Fall of 2017, with pile driving/removal and in-water work occurring during the period of September through November. The second period is scheduled for Spring of 2018, with pile driving/removal and in-water work occurring during the period of March through May.

Pile driving/removal is estimated to occur for a total of about 114 hours over the course of 16 to 50 days.

Specific Geographic Region

The proposed activities will occur at the Gustavus Ferry Terminal located in Gustavus, Alaska on the Icy Passage water body in Southeast Alaska (See Figures 1 and 2 in the Application).

Detailed Description of Activities

ADOT&PF plans to improve the ferry terminal in Gustavus, Alaska. ADOT&PF will remove the existing steel bridge float and restraint structure and replace it with two steel/concrete bridge lift towers capable of elevating the relocated steel transfer bridge above the water when not in use. Each tower would be supported by four 30-inch steel piles. The project would also expand the dock by approximately 4,100 square feet, requiring 34 new 24-inch steel piles; construct a new steel six-pile (24-inch) bridge abutment; relocate the steel transfer bridge, vehicle apron, and aluminum pedestrian gangway; extract 16 steel piles; relocate the log float to the end of the existing float structure (requiring installation of three 12.75-inch steel piles); install a new harbor access float (assembled from a portion of the existing bridge float) and a steel six-pile (30-inch) float restraint structure; and provide access gangways and landing platforms for lift towers and an access catwalk to the existing breasting dolphins. Contractors on previous ADOT&PF dock projects have typically driven piles using the following equipment:

- *Air Impact Hammers:* Vulcan 512/Max Energy 60,000 foot-pounds (ft-lbs); Vulcan 06/Max Energy 19,000 ft-lbs; ICE/Max Energy 19,500 to 60,000 ft-lbs.
- *Diesel Impact Hammer:* Delmag D30/Max Energy 75,970 ft-lbs.
- *Vibratory Hammers:* ICE various models/7,930 to 13,000 pounds static weight.

Similar equipment may be used for the proposed project, though each contractor's equipment may vary.

ADOT&PF anticipates driving one to three piles per day, which accounts for setting the pile in place, positioning the barge while working around existing dock and vessel traffic, splicing sections of pile, and driving the piles. Actual pile driving/removal time for nineteen 12.75-inch-, forty 24-inch-, and fourteen 30-inch-diameter steel piles would be approximately 57 hours of impact driving and 114 hours of vibratory driving over the course of 16 to 50 days in 2017. (See Table 1.)

TABLE 1—PILE-DRIVING SCHEDULE

Description	Project components							
	Dock extension	Bridge abutment	Lift towers	Access float	Log float	Pile removal	Piles installed/ total piles	Installation/ Removal per day
Number of Piles	34	6	8	6	3	16	57/73	3 piles/day (maximum).
Pile Size (Diameter)	24-inch	24-inch	30-inch	30-inch	12.75-inch	12.75-inch		
Total Strikes (Impact)	20,400	3,600	4,800	3,600	1,800	0	34,200	1,800 blows/day.
Total Impact Time	34 hrs	6 hrs	8 hrs	6 hrs	3 hrs	0	57 hrs	3 hrs/day.
Total Vibratory Time	54 hrs	9 hrs	13 hrs	9 hrs	5 hrs	24 hrs	114 hrs	6 hrs/day.

Description of Marine Mammals in the Area of the Specified Activity

Marine waters in Icy Passage support many species of marine mammals, including pinnipeds and cetaceans. There are nine marine mammal species documented in the waters of Icy Passage (Dahlheim *et al.*, 2009; NMFS 2013; and personal communications with Janet Neilson, National Park Service (NPS); Tod Sebens, Cross Sound Express, LLC (CSE); and Stephen Vanderhoff, Spirit Walker Expeditions (SWE)). Two of the species are known to occur near the Gustavus Ferry terminal: The harbor seal and Steller sea lion. The remaining seven species may occur in Icy Passage but less frequently and farther from the ferry terminal: Harbor porpoise, Dall's porpoise, Pacific white-sided dolphin, killer whale, gray whale, humpback whale, and minke whale.

Although listed on the NMFS MMPA mapper (NMFS 2014), gray whale sightings in Icy Strait are very rare and there have been only eight sightings since 1997 (Janet Neilson, NPS, personal communication). None of these sightings were in Icy Passage. Therefore, exposure of the gray whale to project impacts is considered unlikely and take is not requested for this species.

The range of Pacific white-sided dolphin is also suggested to overlap with the project action area as portrayed on the NMFS MMPA mapper, but no sightings have been documented in the project vicinity (Janet Neilson, NPS, personal communication, Dahlheim *et al.*, 2009). Therefore, exposure of the Pacific white-sided dolphin to project impacts is considered unlikely and take is not requested for this species. Table 2 presents the species most likely to occur in the area.

TABLE 2—MARINE MAMMAL SPECIES POTENTIALLY PRESENT IN REGION OF ACTIVITY

Common name	Scientific name	Stock abundance estimate [1]	ESA status	MMPA status	Frequency of occurence [2]
Harbor seal	*Phoca vitulina*	7,210	Not listed	Not Strategic, non-depleted.	Likely.
Steller sea lion	*Eumetopias jubatus*	49,497 (western distinct population segment in Alaska)/60,131 (eastern stock).	Endangered (western Distinct Population Segment).	Strategic, depleted	Likely.
Dall's porpoise	*Phocoenoides dalli*	Unknown	Not listed	Not Strategic, non-depleted.	Infrequent.
Harbor porpoise	*Phocoena phocoena*	11,146	Not listed	Strategic, non-depleted	Likely.

TABLE 2—MARINE MAMMAL SPECIES POTENTIALLY PRESENT IN REGION OF ACTIVITY—Continued

Common name	Scientific name	Stock abundance estimate [1]	ESA status	MMPA status	Frequency of occurence [2]
Humpback whale	*Megaptera novaeangliae.*	10,252	Endangered	Strategic, depleted	Infrequent.
Killer whale	*Orcinus orca*	261 (Northern resident)/587 (Gulf of Alaska transient)/243 (West Coast transient).	Not listed	Strategic, non-depleted	Infrequent.
Minke whale	*Balaenoptera acutorostra.*	Unknown	Not listed	Not Strategic/non-depleted.	Infrequent.

[1] NMFS marine mammal stock assessment reports at: *http://www.nmfs.noaa.gov/pr/sars/species.htm.*

[2] Infrequent: Confirmed, but irregular sightings; Likely: Confirmed and regular sightings of the species in the area year-round.

Although they are documented near the ferry terminal, harbor seal populations in Glacier Bay are declining (Janet Neilson, NPS, personal communication). It is estimated that less than 10 individuals are typically seen near the ferry dock during charter boat operations in the spring and summer (Tod Sebens, CSE, Stephen Vanderhoff, SWE, personal communication). Steller sea lions are common in the ferry terminal area during the charter fishing season (May to September) and are known to haul out on the public dock (Bruce Kruger, Alaska Department of Fish and Game (ADF&G), personal communication). The nearest natural Steller sea lion haulout sites are located on Black Rock on the south side of Pleasant Island and Carolus Point west of Point Gustavus (Mathews *et al.*, 2011).

There are confirmed sightings of Dall's porpoise, harbor porpoise, humpback whale, killer whale, and minke whale in Icy Passage (Janet Neilson, NPS, Tod Sebens, CSE, Stephen Vanderhoff, SWE, personal communication). However, sightings are less frequent in Icy Passage than in Icy Strait. Opportunistic sightings of marine mammals by NPS during humpback whale surveys and whale watching tour companies operating out of Gustavus (CSE and WSE operate 100 days of tours in the May to September season), provide the following estimates for each spring/summer season:

- Harbor porpoise are seen in Icy Passage on about 75+ percent of trips.
- Three to four minke whale sightings/season in Icy Strait. One or two in Icy Passage.
- Dall's porpoise have four to 12 sightings/season, mostly in Icy Strait.
- Killer whales have about 12 sightings/season in Icy Strait and one or two sightings a year in Icy Passage.
- Humpback whale sightings in Icy Passage are infrequent but on occasion they are seen between the ferry terminal and Pleasant Island (Stephen Vanderhoff, SWE, personal communication).

By most measures, the populations of marine mammals that utilize Icy Strait are healthy and increasing. Populations of humpback whales using Glacier Bay and surrounding areas are increasing by 5.1 percent per year (Hendrix *et al.* 2012). Steller sea lions have increased in the Glacier Bay region by 8.2 percent per year from the 1970's to 2009, representing the highest rate of growth for this species in Alaska (Mathews *et al.* 2011). In addition, a Steller sea lion rookery and several haulouts have recently been established in the Glacier Bay region (Womble *et al.* 2009).

In the species accounts provided here, we offer a brief introduction to the species and relevant stock that are likely to be taken as well as available information regarding population trends and threats, and describe any information regarding local occurrence.

Harbor Seal

Harbor seals occurring in Icy Passage belong to the Glacier Bay/Icy Strait (GB/IS) harbor seal stock. The current statewide abundance estimate for this stock is 7,210 (Muto and Angliss 2015). The GB/IS harbor seals have been rapidly declining despite stable or slightly increasing trends in nearby populations (Womble and Gende 2013). A suite of recent studies suggest that (1) harbor seals in Glacier Bay are not significantly stressed due to nutritional constraints, (2) the clinical health and disease status of seals within Glacier Bay is not different than seals from other stable or increasing populations, and (3) disturbance by vessels does not appear to be a primary factor driving the decline. Long-term monitoring of harbor seals on glacial ice has occurred in Glacier Bay since the 1970s and has shown this area to support one of the largest breeding aggregations in Alaska. After a dramatic retreat of Muir Glacier, in the East Arm of Glacier Bay, between 1973 and 1986 (more than 7 kilometers) and the subsequent grounding and cessation of calving in 1993, floating glacial ice was greatly reduced as a haulout substrate for harbor seals and ultimately resulted in the abandonment of upper Muir Inlet by harbor seals.

Steller Sea Lion

Steller sea lions occurring in Icy Passage could belong to either the western or eastern U.S. stock. The current total population estimate for the western stock in Alaska is estimated at 49,497 based on 2014 survey results (Muto and Angliss 2015). To get this estimate, pups were counted during the breeding season, and the number of births is estimated from the pup count. The western stock in Alaska shows a positive population trend estimate of 1.67 percent.

The current total population estimate for the eastern stock of Steller sea lions is estimated at 60,131 based on counts made between 2009 and 2014 (Muto and Angliss 2015). To get this estimate, pups were counted during the breeding season, and the number of births is estimated from the pup count. The best available information indicates the eastern stock of Steller sea lion increased at a rate of 4.18 percent per year (90 percent confidence bounds of 3.71 to 4.62 percent per year) between 1979 and 2010 based on an analysis of pup counts in California, Oregon, British Columbia, and Southeast Alaska.

Dall's Porpoise

There are no reliable abundance data for the Alaska stock of Dall's porpoise. Surveys for the Alaska stock of Dall's porpoise are greater than 21 years old (Allen and Angliss 2014). A population estimate from 1987 to 1991 was 83,400. Since the abundance estimate is based on data older than eight years, NMFS does not consider the estimate to be valid and the minimum population number is also considered unknown.

Harbor Porpoise

There are three harbor porpoise stocks in Alaska, including the Southeast Alaska stock, Gulf of Alaska stock, and the Bering Sea stock. Only the Southeast Alaska stock occurs in the project vicinity. Harbor porpoise numbers for the Southeast Alaska stock are estimated at 11,146 animals (Allen and Angliss 2014). Abundance estimates for harbor porpoise occupying the inland waters of Southeast Alaska were 1,081 in 2012. However, this number may be biased low due to survey methodology.

Humpback Whale

The central North Pacific stock of humpback whales occurs in the project area. Estimates of this stock are determined by winter surveys in Hawaiian waters. Point estimates of abundance for Hawaii ranged from 7,469 to 10,252; the estimate from the best model was 10,252 (Muto and Angliss 2015). Using the population estimate of 10,252, the minimum estimate for the central North Pacific humpback whale stock is 9,896 (Muto and Angliss 2015).

Since 1985, the NPS has been monitoring humpback whales in both Glacier Bay National Park and Icy Strait and has published annual reports (*http://www.nps.gov/glba/naturescience/whale_acoustic_reports.htm*). The NPS typically surveys Icy Strait, located south of Icy Passage, once a week between June 1 and August 31, with most survey effort focused in the area east of Point Gustavus and Pleasant Island. In 2013, 202 humpback whales were documented in Icy Strait during the NPS monitoring period; this was a 14 percent increase over the previous high count of 177 whales in 2012 (Neilson *et al.,* 2014). However, in 2014, a 39 percent decrease in abundance was observed, with only 124 whales documented in Icy Strait. The reasons for this decline in local abundance is not known, but NPS speculated that a magnitude 6.1 earthquake centered in Palma Bay that occurred on July 25, 2014, may have caused unfavorable environmental conditions in the Glacier Bay region. The earthquake and aftershocks caused one or more submarine landslides that increased turbidity in the region and may have decreased humpback whale foraging success over a period of several weeks in lower Glacier Bay and Icy Strait. In response, humpback whales may have shifted their distribution to other areas, such as Frederick Sound, seeking better foraging conditions (Neilson *et al.,* 2015).

Humpback whales are present in Southeast Alaska in all months of the year, but at substantially lower numbers in the fall and winter. At least 10 individuals were found to over-winter near Sitka, and NMFS researchers have documented one whale that over-wintered near Juneau. It is unknown how common over-wintering behavior is in most areas because there is minimal or no photographic identification effort in the winter in most parts of Southeast Alaska. Late fall and winter whale habitat in Southeast Alaska appears to correlate with areas that have over-wintering herring (lower Lynn Canal, Tenakee Inlet, Whale Bay, Ketchikan, Sitka Sound). In Glacier Bay and Icy Strait, the longest sighting interval recorded by NPS was over a span of 219 days, between April 17 and November 21, 2002, but overwintering in this region is expected to be low (Gabriele *et al.,* 2015).

Killer Whale

Killer whales occurring in Icy Passage could belong to one of three different stocks: Eastern North Pacific Northern residents stock (Northern residents); Gulf of Alaska, Aleutian Islands, and Bering Sea transient stock (Gulf of Alaska transients); or West Coast transient stock. The Northern resident stock is a transboundary stock, and includes killer whales that frequent British Columbia, Canada, and southeastern Alaska (Allen and Angliss 2014). Photo-identification studies since 1970 have catalogued every individual belonging to the Northern resident stock and in 2010 the population was composed of three clans representing a total of 261 whales.

In recent years, a small number of the Gulf of Alaska transients (identified by genetics and association) have been seen in southeastern Alaska; previously only West Coast transients had been seen in the region (Allen and Angliss 2014). Therefore, the Gulf of Alaska transient stock occupies a range that includes southeastern Alaska. Photo-identification studies have identified 587 individual whales in this stock.

The West Coast transient stock includes animals that occur in California, Oregon, Washington, British Columbia, and southeastern Alaska. Analysis of photographic data identifies 243 individual transient killer whales (Muto and Angliss 2015). The total number of transient killer whales reported above should be considered a minimum count for the West Coast transient stock.

Minke Whale

The Alaska stock of minke whales occurs in Icy Strait and Southeast Alaska. At this time, it is not possible to produce a reliable estimate of minimum abundance for this wide ranging stock. No estimates have been made for the number of minke whales in the entire North Pacific. Surveys of the Bering Sea, and from Kenai Fjords in the Gulf of Alaska to the central Aleutian Islands, estimate 1,003 and 1,233 animals, respectively (Allen and Angliss 2014).

Potential Effects of the Specified Activity on Marine Mammals and Their Habitat

This section includes a summary and discussion of the ways that stressors, (*e.g.,* pile driving) and potential mitigation activities, associated with the improvements at Gustavus Ferry Terminal may impact marine mammals and their habitat. The *Estimated Take by Incidental Harassment* section later in this document will include an analysis of the number of individuals that are expected to be taken by this activity. The *Negligible Impact Analysis* section will include the analysis of how this specific activity will impact marine mammals and will consider the content of this section, the *Estimated Take by Incidental Harassment* section, and the *Proposed Mitigation* section to draw conclusions regarding the likely impacts of this activity on the reproductive success or survivorship of individuals and from that on the affected marine mammal populations or stocks. In the following discussion, we provide general background information on sound and marine mammal hearing before considering potential effects to marine mammals from sound produced by impact and vibratory pile driving.

Description of Sound Sources

Sound travels in waves, the basic components of which are frequency, wavelength, velocity, and amplitude. Frequency is the number of pressure waves that pass by a reference point per unit of time and is measured in hertz (Hz) or cycles per second. Wavelength is the distance between two peaks of a sound wave; lower frequency sounds have longer wavelengths than higher frequency sounds and attenuate (decrease) more rapidly in shallower water. Amplitude is the height of the sound pressure wave or the loudness of a sound and is typically measured using the decibel (dB) scale. A dB is the ratio between a measured pressure (with sound) and a reference pressure (sound at a constant pressure, established by scientific standards). It is a logarithmic unit that accounts for large variations in amplitude; therefore, relatively small changes in dB ratings correspond to large changes in sound pressure. When referring to sound pressure levels (SPLs; the sound force per unit area), the reference intensity for sound in water is one micropascal (μPa). One pascal is the pressure resulting from a force of one newton exerted over an area of one square meter. The source level (SL) represents the sound level at a distance of 1 m from the source (referenced to 1 μPa). The received level is the sound level at the listener's position. Note that all underwater sound levels in this document are referenced to a pressure of 1 μPa and all airborne sound levels in this document are referenced to a pressure of 20 μPa.

Root mean square (rms) is the quadratic mean sound pressure over the duration of an impulse. Rms is calculated by squaring all of the sound amplitudes, averaging the squares, and then taking the square root of the average (Urick, 1983). Rms accounts for both positive and negative values; squaring the pressures makes all values positive so that they may be accounted for in the summation of pressure levels (Hastings and Popper, 2005). This measurement is often used in the context of discussing behavioral effects, in part because behavioral effects, which often result from auditory cues, may be better expressed through averaged units than by peak pressures.

When underwater objects vibrate or activity occurs, sound pressure waves are created. These waves alternately compress and decompress the water as the sound wave travels. Underwater sound waves radiate in all directions away from the source (similar to ripples on the surface of a pond), except in cases where the source is directional. The compressions and decompressions associated with sound waves are detected as changes in pressure by aquatic life and man-made sound receptors such as hydrophones.

Even in the absence of sound from the specified activity, the underwater environment is typically loud due to ambient sound. Ambient sound is defined as environmental background sound levels lacking a single source or point (Richardson *et al.*, 1995), and the sound level of a region is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (*e.g.*, waves, earthquakes, ice, atmospheric sound), biological (*e.g.*, sounds produced by marine mammals, fish, and invertebrates), and anthropogenic sound (*e.g.*, vessels, dredging, aircraft, construction). A number of sources contribute to ambient sound, including the following (Richardson *et al.*, 1995):

- *Wind and waves:* The complex interactions between wind and water surface, including processes such as breaking waves and wave-induced bubble oscillations and cavitation, are a main source of naturally occurring ambient noise for frequencies between 200 Hz and 50 kHz (Mitson, 1995). In general, ambient sound levels tend to increase with increasing wind speed and wave height. Surf noise becomes important near shore, with measurements collected at a distance of 8.5 km from shore showing an increase of 10 dB in the 100 to 700 Hz band during heavy surf conditions.
- *Precipitation:* Sound from rain and hail impacting the water surface can become an important component of total noise at frequencies above 500 Hz, and possibly down to 100 Hz during quiet times.
- *Biological:* Marine mammals can contribute significantly to ambient noise levels, as can some fish and shrimp. The frequency band for biological contributions is from approximately 12 Hz to over 100 kHz.
- *Anthropogenic:* Sources of ambient noise related to human activity include transportation (surface vessels and aircraft), dredging and construction, oil and gas drilling and production, seismic surveys, sonar, explosions, and ocean acoustic studies. Shipping noise typically dominates the total ambient noise for frequencies between 20 and 300 Hz. In general, the frequencies of anthropogenic sounds are below 1 kHz and, if higher frequency sound levels are created, they attenuate rapidly (Richardson *et al.*, 1995). Sound from identifiable anthropogenic sources other than the activity of interest (*e.g.*, a passing vessel) is sometimes termed background sound, as opposed to ambient sound. Representative levels of anthropogenic sound are displayed in Table 3.

The sum of the various natural and anthropogenic sound sources at any given location and time—which comprise "ambient" or "background" sound—depends not only on the source levels (as determined by current weather conditions and levels of biological and shipping activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10–20 dB from day to day (Richardson *et al.*, 1995). The result is that, depending on the source type and its intensity, sound from the specified activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals.

TABLE 3—REPRESENTATIVE SOUND LEVELS OF ANTHROPOGENIC SOURCES

Sound source	Frequency range (Hz)	Underwater sound level	Reference
Small vessels	250–1,000	151 dB rms at 1 m	Richardson *et al.*, 1995.
Tug docking gravel barge	200–1,000	149 dB rms at 100 m	Blackwell and Greene, 2002.
Vibratory driving of 72-in steel pipe pile	10–1,500	180 dB rms at 10 m	Reyff, 2007.
Impact driving of 36-in steel pipe pile	10–1,500	195 dB rms at 10 m	Laughlin, 2007.
Impact driving of 66-in cast-in-steel-shell (CISS) pile.	10–1,500	195 dB rms at 10 m	Reviewed in Hastings and Popper, 2005.

High levels of vessel traffic are known to elevate background levels of noise in the marine environment. For example, continuous sounds for tugs pulling barges have been reported to range from 145 to 166 dB re 1 μPa rms at 1 meter from the source (Miles *et al.*, 1987; Richardson *et al.*, 1995; Simmonds *et al.*, 2004). Ambient underwater noise levels in Gustavus Ferry Terminal project area are both variable and relatively high, and are expected to mask some sounds of pile installation and pile extraction.

In-water construction activities associated with the project include impact and vibratory pile driving and removal. There are two general categories of sound types: Impulse and non-pulse (defined in the following). Vibratory pile driving is considered to be continuous or non-pulsed while impact pile driving is considered to be an impulse or pulsed sound type. The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (*e.g.*, Ward, 1997 in Southall *et al.*, 2007). Please see Southall *et al.* (2007) for an in-depth discussion of these concepts. Note that information related to impact hammers is included here for comparison.

Pulsed sound sources (*e.g.*, explosions, gunshots, sonic booms, impact pile driving) produce signals that are brief (typically considered to be less than one second), broadband, atonal transients (ANSI, 1986; Harris, 1998; NIOSH, 1998; ISO, 2003; ANSI, 2005) and occur either as isolated events or repeated in some succession. Pulsed sounds are all characterized by a relatively rapid rise from ambient pressure to a maximal pressure value followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features.

Non-pulsed sounds can be tonal, narrowband, or broadband, brief or prolonged, and may be either continuous or non-continuous (ANSI, 1995; NIOSH, 1998). Some of these non-pulsed sounds can be transient signals of short duration but without the essential properties of pulses (*e.g.*, rapid rise time). Examples of non-pulsed sounds include those produced by vessels, aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems (such as those used by the U.S. Navy). The duration of such sounds, as received at a distance, can be greatly extended in a highly reverberant environment.

The likely or possible impacts of the proposed pile driving program at the Gustavus Ferry Terminal on marine mammals could involve both non-acoustic and acoustic stressors. Potential non-acoustic stressors could result from the physical presence of the equipment and personnel. Any impacts to marine mammals are expected to primarily be acoustic in nature. Acoustic stressors could include effects of heavy equipment operation and pile installation and pile removal at the Ferry Terminal.

Marine Mammal Hearing

When considering the influence of various kinds of sound on the marine environment, it is necessary to understand that different kinds of marine life are sensitive to different frequencies of sound. Based on available behavioral data, audiograms have been derived using auditory evoked potentials, anatomical modeling, and other data, Southall *et al.*, (2007) designate "functional hearing groups" for marine mammals and estimate the lower and upper frequencies of functional hearing of the groups. The functional groups and the associated frequencies are indicated below (though animals are less sensitive to sounds at the outer edge of their functional range and most sensitive to sounds of frequencies within a smaller range somewhere in the middle of their functional hearing range):

- *Low-frequency cetaceans (mysticetes):* Functional hearing is estimated to occur between approximately 7 Hz and 25 kHz (extended from 22 kHz; Watkins, 1986; Au *et al.*, 2006; Lucifredi and Stein, 2007; Ketten and Mountain, 2009; Tubelli *et al.*, 2012);
- *Mid-frequency cetaceans (larger toothed whales, beaked whales, and most delphinids):* Functional hearing is estimated to occur between approximately 150 Hz and 160 kHz;
- *High-frequency cetaceans (porpoises, river dolphins, and members of the genera* Kogia *and* Cephalorhynchus; *now considered to include two members of the genus* Lagenorhynchus *on the basis of recent echolocation data and genetic data [May-Collado and Agnarsson, 2006; Kyhn* et al., *2009, 2010; Tougaard* et al., *2010]):* Functional hearing is estimated to occur between approximately 200 Hz and 180 kHz; and
- *Pinnipeds in water:* Functional hearing is estimated to occur between approximately 75 Hz to 100 kHz for Phocidae (true seals) and between 100 Hz and 48 kHz for Otariidae (eared seals), with the greatest sensitivity between approximately 700 Hz and 20 kHz. The pinniped functional hearing group was modified from Southall *et al.*, (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.*, 2006; Kastelein *et al.*, 2009; Reichmuth *et al.*, 2013).

As mentioned previously in this document, seven marine mammal species (five cetacean and two pinniped) may occur in the project area. Of the seven species likely to occur in the proposed project area, two are classified as low frequency cetaceans (*i.e.*, humpback whale, minke whale), one is classified as a mid-frequency cetacean (*i.e.*, killer whale), and two are classified as high-frequency cetaceans (*i.e.*, harbor porpoise, Dall's porpoise) (Southall *et al.*, 2007). Additionally, harbor seals are classified as members of the phocid pinnipeds in water functional hearing group, while Steller sea lions are grouped under the Otariid pinnipeds in water functional hearing group. A species' functional hearing group is a consideration when we analyze the effects of exposure to sound on marine mammals.

Acoustic Impacts

Potential Effects of Pile Driving Sound—The effects of sounds from pile driving might result in one or more of the following: Temporary or permanent hearing impairment; non-auditory physical or physiological effects; behavioral disturbance; and masking (Richardson *et al.*, 1995; Gordon *et al.*, 2004; Nowacek *et al.*, 2007; Southall *et al.*, 2007). The effects of pile driving on marine mammals are dependent on several factors, including: The size, type, and depth of the animal; the depth, intensity, and duration of the pile driving sound; the depth of the water column; the substrate of the habitat; the standoff distance between the pile and the animal; and the sound propagation properties of the environment. Impacts to marine mammals from pile driving activities are expected to result primarily from acoustic pathways. As such, the degree of effect is intrinsically related to the received level and duration of the sound exposure, which are in turn influenced by the distance between the animal and the source. The further away from the source, the less intense the exposure should be. The substrate and depth of the habitat affect the sound propagation properties of the environment. Shallow environments are typically more structurally complex, which leads to rapid sound attenuation. In addition, substrates that are soft (*e.g.*, sand) would absorb or attenuate the sound more readily than hard substrates (*e.g.*, rock) which may reflect the acoustic wave. Soft porous substrates would also likely require less time to drive the pile, and possibly less forceful equipment, which would ultimately decrease the intensity of the acoustic source.

In the absence of mitigation, impacts to marine species would be expected to result from physiological and behavioral responses to both the type and strength of the acoustic signature (Viada *et al.*, 2008). The type and severity of behavioral impacts are more difficult to define due to limited studies addressing the behavioral effects of impulse sounds on marine mammals. Potential effects from impulse sound sources can range in severity from effects such as behavioral disturbance or tactile perception to physical discomfort, slight injury of the internal organs and the auditory system, or mortality (Yelverton *et al.*, 1973).

Hearing Impairment and Other Physical Effects—Marine mammals exposed to high intensity sound repeatedly or for prolonged periods can experience hearing threshold shift (TS), which is the loss of hearing sensitivity at certain frequency ranges (Kastak *et al.*, 1999; Schlundt *et al.*, 2000; Finneran *et al.*, 2002, 2005). TS can be permanent (PTS), in which case the loss of hearing sensitivity is not recoverable, or temporary (TTS), in which case the animal's hearing threshold would recover over time (Southall *et al.*, 2007). Marine mammals depend on acoustic cues for vital biological functions, (*e.g.*, orientation, communication, finding prey, avoiding predators); thus, TTS may result in reduced fitness in survival and reproduction. However, this depends on the frequency and duration of TTS, as well as the biological context in which it occurs. TTS of limited duration, occurring in a frequency range that does not coincide with that used for recognition of important acoustic cues, would have little to no effect on an animal's fitness. Repeated sound exposure that leads to TTS could cause PTS. PTS constitutes injury, but TTS does not (Southall *et al.*, 2007). The following subsections discuss in somewhat more detail the possibilities of TTS, PTS, and non-auditory physical effects.

Temporary Threshold Shift—TTS is the mildest form of hearing impairment that can occur during exposure to a strong sound (Kryter, 1985). While experiencing TTS, the hearing threshold rises, and a sound must be stronger in order to be heard. In terrestrial mammals, TTS can last from minutes or hours to days (in cases of strong TTS). For sound exposures at or somewhat above the TTS threshold, hearing sensitivity in both terrestrial and marine mammals recovers rapidly after exposure to the sound ends. Few data on sound levels and durations necessary to elicit mild TTS have been obtained for marine mammals, and none of the published data concern TTS elicited by exposure to multiple pulses of sound. Available data on TTS in marine mammals are summarized in Southall *et al.* (2007).

Given the available data, the received level of a single pulse (with no frequency weighting) might need to be approximately 186 dB re 1 μPa^2 − s (*i.e.*, 186 dB sound exposure level (SEL) or approximately 221–226 dB p–p (peak)) in order to produce brief, mild TTS. Exposure to several strong pulses that each have received levels near 190 dB rms (175–180 dB SEL) might result in cumulative exposure of approximately 186 dB SEL and thus slight TTS in a small odontocete, assuming the TTS threshold is (to a first approximation) a function of the total received pulse energy.

The above TTS information for odontocetes is derived from studies on the bottlenose dolphin (*Tursiops truncatus*) and beluga whale (*Delphinapterus leucas*). There is no published TTS information for other species of cetaceans. However, preliminary evidence from a harbor porpoise exposed to pulsed sound suggests that its TTS threshold may have been lower (Lucke *et al.*, 2009). As summarized above, data that are now available imply that TTS is unlikely to occur unless odontocetes are exposed to pile driving pulses stronger than 180 dB re 1 μPa (rms).

Permanent Threshold Shift—When PTS occurs, there is physical damage to the sound receptors in the ear. In severe cases, there can be total or partial deafness, while in other cases the animal has an impaired ability to hear sounds in specific frequency ranges (Kryter, 1985). There is no specific evidence that exposure to pulses of sound can cause PTS in any marine mammal. However, given the possibility that mammals close to a sound source can incur TTS, it is possible that some individuals might incur PTS. Single or occasional occurrences of mild TTS are not indicative of permanent auditory damage, but repeated or (in some cases) single exposures to a level well above that causing TTS onset might elicit PTS.

PTS is considered auditory injury (Southall *et al.*, 2007). Irreparable damage to the inner or outer cochlear hair cells may cause PTS, however, other mechanisms are also involved, such as exceeding the elastic limits of certain tissues and membranes in the middle and inner ears and resultant changes in the chemical composition of the inner ear fluids (Southall *et al.*, 2007).

Relationships between TTS and PTS thresholds have not been studied in marine mammals but are assumed to be similar to those in humans and other terrestrial mammals, based on anatomical similarities. PTS might occur at a received sound level at least several dB above that inducing mild TTS if the animal were exposed to strong sound pulses with rapid rise time. Based on data from terrestrial mammals, a precautionary assumption is that the PTS threshold for impulse sounds (such as pile driving pulses as received close to the source) is at least 6 dB higher than the TTS threshold on a peak-pressure basis and probably greater than 6 dB (Southall *et al.*, 2007). On an SEL basis, Southall *et al.*, (2007) estimated that received levels would need to exceed the TTS threshold by at least 15 dB for there to be risk of PTS. Thus, for cetaceans, Southall *et al.*, (2007) estimate that the PTS threshold might be an M-weighted SEL (for the sequence of received pulses) of approximately 198 dB re 1 μPa^2-s (15 dB higher than the TTS threshold for an impulse). Given the higher level of sound necessary to cause PTS as compared with TTS, it is considerably less likely that PTS could occur.

Measured source levels from impact pile driving can be as high as 214 dB rms. Although no marine mammals have been shown to experience TTS or PTS as a result of being exposed to pile driving activities, captive bottlenose dolphins and beluga whales exhibited changes in behavior when exposed to strong pulsed sounds (Finneran *et al.*, 2000, 2002, 2005). The animals tolerated high received levels of sound before exhibiting aversive behaviors. Experiments on a beluga whale showed that exposure to a single watergun impulse at a received level of 207 kPa (30 psi) p-p, which is equivalent to 228 dB p-p, resulted in a 7 and 6 dB TTS in the beluga whale at 0.4 and 30 kHz, respectively. Thresholds returned to within 2 dB of the pre-exposure level within four minutes of the exposure (Finneran *et al.*, 2002). Although the source level of pile driving from one hammer strike is expected to be much lower than the single watergun impulse cited here, animals being exposed for a prolonged period to repeated hammer strikes could receive more sound exposure in terms of SEL than from the single watergun impulse (estimated at 188 dB re 1 μPa^2-s) in the aforementioned experiment (Finneran *et al.*, 2002). However, in order for marine mammals to experience TTS or PTS, the animals have to be close enough to be exposed to high intensity sound levels for a prolonged period of time. Based on the best scientific information available, these SPLs are far below the thresholds that could cause TTS or the onset of PTS.

Non-auditory Physiological Effects—Non-auditory physiological effects or injuries that theoretically might occur in marine mammals exposed to strong underwater sound include stress, neurological effects, bubble formation, resonance effects, and other types of organ or tissue damage (Cox *et al.*, 2006; Southall *et al.*, 2007). Studies examining such effects are limited. In general, little is known about the potential for pile driving to cause auditory impairment or other physical effects in marine mammals. Available data suggest that such effects, if they occur at all, would presumably be limited to short distances from the sound source and to activities that extend over a prolonged period. The available data do not allow identification of a specific exposure level above which non-auditory effects can be expected (Southall *et al.*, 2007) or any meaningful quantitative predictions of the numbers (if any) of marine mammals that might be affected in those ways. Marine mammals that show behavioral avoidance of pile driving, including some odontocetes and some pinnipeds, are especially unlikely to incur auditory impairment or non-auditory physical effects.

Disturbance Reactions

Disturbance includes a variety of effects, including subtle changes in behavior, more conspicuous changes in activities, and displacement. Behavioral responses to sound are highly variable and context-specific and reactions, if any, depend on species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day, and many other factors (Richardson *et al.*, 1995; Wartzok *et al.*, 2003; Southall *et al.*, 2007).

Habituation can occur when an animal's response to a stimulus wanes with repeated exposure, usually in the absence of unpleasant associated events (Wartzok *et al.*, 2003). Animals are most likely to habituate to sounds that are predictable and unvarying. The opposite process is sensitization, when an unpleasant experience leads to subsequent responses, often in the form of avoidance, at a lower level of exposure. Behavioral state may affect the type of response as well. For example, animals that are resting may show greater behavioral change in response to disturbing sound levels than animals that are highly motivated to remain in an area for feeding (Richardson *et al.*, 1995; NRC, 2003; Wartzok *et al.*, 2003).

Controlled experiments with captive marine mammals showed pronounced behavioral reactions, including avoidance of loud sound sources (Ridgway *et al.*, 1997; Finneran *et al.*, 2003). Observed responses of wild marine mammals to loud pulsed sound sources (typically seismic guns or acoustic harassment devices, but also including pile driving) have been varied but often consist of avoidance behavior or other behavioral changes suggesting discomfort (Morton and Symonds, 2002; Thorson and Reyff, 2006; see also Gordon *et al.*, 2004; Wartzok *et al.*, 2003; Nowacek *et al.*, 2007). Responses to continuous sound, such as vibratory pile installation, have not been documented as well as responses to pulsed sounds.

With both types of pile driving, it is likely that the onset of pile driving could result in temporary, short term changes in an animal's typical behavior and/or avoidance of the affected area. These behavioral changes may include (Richardson *et al.*, 1995): Changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); avoidance of areas where sound sources are located; and/or flight responses (*e.g.*, pinnipeds flushing into water from haul-outs or rookeries). Pinnipeds may increase their haul-out time, possibly to avoid in-water disturbance (Thorson and Reyff, 2006).

The biological significance of many of these behavioral disturbances is difficult to predict. However, the consequences of behavioral modification could be expected to be biologically significant if the change affects growth, survival, or reproduction. Significant behavioral modifications that could potentially lead to effects on growth, survival, or reproduction include:

- Changes in diving/surfacing patterns;
- Habitat abandonment due to loss of desirable acoustic environment; and
- Cessation of feeding or social interaction.

The onset of behavioral disturbance from anthropogenic sound depends on both external factors (characteristics of sound sources and their paths) and the specific characteristics of the receiving animals (hearing, motivation, experience, demography) and is difficult to predict (Southall *et al.*, 2007).

Auditory Masking—Natural and artificial sounds can disrupt behavior by masking, or interfering with, a marine mammal's ability to hear other sounds. Masking occurs when the receipt of a sound is interfered with by another coincident sound at similar frequencies and at similar or higher levels. Chronic exposure to excessive, though not high-intensity, sound could cause masking at particular frequencies for marine mammals that utilize sound for vital biological functions. Masking can interfere with detection of acoustic signals such as communication calls, echolocation sounds, and environmental sounds important to marine mammals. It is important to distinguish TTS and PTS, which persist after the sound exposure, from masking, which occurs only during the sound exposure. Because masking (without resulting in TS) is not associated with abnormal physiological function, it is not considered a physiological effect, but rather a potential behavioral effect.

Masking occurs at specific frequency bands, so understanding the frequencies that the animals utilize is important in determining any potential behavioral impacts. Because sound generated from in-water vibratory pile driving is mostly concentrated at low frequency ranges, it may have less effect on high frequency echolocation sounds made by porpoises. However, lower frequency man-made sounds are more likely to affect detection of communication calls and other potentially important natural sounds, such as surf and prey sound. It may also affect communication signals when they occur near the sound band and thus reduce the communication space of animals (*e.g.*, Clark *et al.*, 2009) and cause increased stress levels (*e.g.*, Foote *et al.*, 2004; Holt *et al.*, 2009).

Masking has the potential to impact species at the population or community levels as well as at individual levels. Masking affects both senders and receivers of the signals and can potentially in certain circumstances have long-term chronic effects on marine mammal species and populations. Recent research suggests that low frequency ambient sound levels have increased by as much as 20 dB (more than three times in terms of SPL) in the world's ocean from pre-industrial periods, and that most of these increases are from distant shipping (Hildebrand, 2009). All anthropogenic sound sources, such as those from vessel traffic, pile driving, and dredging activities, contribute to the elevated ambient sound levels, thus intensifying masking.

Vibratory pile driving may potentially mask acoustic signals important to marine mammal species. However, the short-term duration and limited affected area would result in insignificant impacts from masking.

Acoustic Effects, Airborne—Pinnipeds that occur near the project site could be exposed to airborne sounds associated with pile driving that have the potential to cause behavioral harassment, depending on their distance from pile driving activities. Cetaceans are not expected to be exposed to airborne sounds that would result in harassment as defined under the MMPA.

Airborne noise will primarily be an issue for pinnipeds that are swimming at the surface or hauled out near the project site within the range of noise levels elevated above the acoustic criteria in Table 4 below. We recognize that pinnipeds in the water could be exposed to airborne sound that may result in behavioral harassment when looking with heads above water. Most likely, airborne sound would cause behavioral responses similar to those discussed above in relation to underwater sound. For instance, anthropogenic sound could cause hauled-out pinnipeds to exhibit changes in their normal behavior, such as reduction in vocalizations, or cause them to temporarily abandon the area and move further from the source. However, these animals would previously have been taken as a result of exposure to underwater sound above the behavioral harassment thresholds, which are in all cases larger than those associated with airborne sound. Thus, the behavioral harassment of these animals is already accounted for in these estimates of potential take. Multiple incidents of exposure to sound above NMFS' thresholds for behavioral harassment are not believed to result in increased behavioral disturbance, in either nature or intensity of disturbance reaction. Therefore, we do not believe that authorization of incidental take resulting from airborne sound for pinnipeds is warranted, and airborne sound is not discussed further here.

Vessel Interaction

Besides being susceptible to vessel strikes, cetacean and pinniped responses to vessels may result in behavioral changes, including: Greater variability in the dive, surfacing, and respiration patterns; changes in vocalizations; and changes in swimming speed or direction (NRC, 2003). There will be a temporary and localized increase in vessel traffic during construction.

Potential Effects on Marine Mammal Habitat

The primary potential impacts to marine mammal habitat are associated with elevated sound levels produced by vibratory and impact pile driving and removal in the area. However, other potential impacts to the surrounding habitat from physical disturbance are also possible.

Potential Pile Driving Effects on Prey—Construction activities would produce continuous (*i.e.,* vibratory pile driving, down-hole drilling) sounds and pulsed (*i.e.,* impact driving) sounds.

Fish react to sounds that are especially strong and/or intermittent low-frequency sounds. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. Hastings and Popper (2005) identified several studies that suggest fish may relocate to avoid certain areas of sound energy. Additional studies have documented effects of pile driving on fish, although several are based on studies in support of large, multiyear bridge construction projects (*e.g.,* Scholik and Yan, 2001, 2002; Popper and Hastings, 2009). Sound pulses at received levels of 160 dB may cause subtle changes in fish behavior. SPLs of 180 dB may cause noticeable changes in behavior (Pearson *et al.,* 1992; Skalski *et al.,* 1992). SPLs of sufficient strength have been known to cause injury to fish and fish mortality.

The most likely impact to fish from pile driving activities at the project area would be temporary behavioral avoidance of the area. The duration of fish avoidance of this area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution and behavior is anticipated. In general, impacts to marine mammal prey species are expected to be minor and temporary due to the short timeframe for the project.

Effects to Foraging Habitat—Pile installation may temporarily increase turbidity resulting from suspended sediments. Any increases would be temporary, localized, and minimal. ADOT&PF must comply with state water quality standards during these operations by limiting the extent of turbidity to the immediate project area. In general, turbidity associated with pile installation is localized to about a 25-foot radius around the pile (Everitt *et al.,* 1980). Cetaceans are not expected to be close enough to the project pile driving areas to experience effects of turbidity, and any pinnipeds will be transiting the area and could avoid localized areas of turbidity. Therefore, the impact from increased turbidity levels is expected to be discountable to marine mammals. Furthermore, pile driving and removal at the project site will not obstruct movements or migration of marine mammals.

Proposed Mitigation Measures

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, "and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking" for certain subsistence uses. NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting such activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, their habitat. 50 CFR 216.104(a)(11). For the proposed project, ADOT&PF worked with NMFS and proposed the following mitigation measures to minimize the potential impacts to marine mammals in the project vicinity. The primary purposes of these mitigation measures are to minimize sound levels from the activities, and to shut down operations and monitor marine mammals within designated zones of influence corresponding to NMFS' current Level A and B harassment thresholds, which are depicted in Table 5 found later in the *Estimated Take by Incidental Harassment* section.

In addition to the measures described later in this section, ADOT&PF would employ the following standard mitigation measures:

(a) Conduct briefings between construction supervisors and crews, and marine mammal monitoring team, prior to the start of all pile driving activity, and when new personnel join the work, in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures.

(b) For in-water heavy machinery work other than pile driving (*e.g.,* standard barges, tug boats, barge-mounted excavators, or clamshell equipment used to place or remove material), if a marine mammal comes within 10 m, operations shall cease and vessels shall reduce speed to the minimum level required to maintain steerage and safe working conditions. This type of work could include the following activities: (1) Movement of the barge to the pile location; or (2) positioning of the pile on the substrate via a crane (*i.e.,* stabbing the pile).

(c) To limit the amount of waterborne noise, a vibratory hammer will be used for initial driving, followed by an impact hammer to proof the pile to required load-bearing capacity.

Establishment of Shutdown Zone—For all pile driving activities, ADOT&PF will establish a shutdown zone. Shutdown zones are intended to contain the area in which SPLs equal or exceed the 180/190 dB (rms) acoustic injury threshold, with the purpose being to define an area within which shutdown of activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area), thus preventing injury of marine mammals. Nominal radial distances for shutdown zones are shown in Table 5.

Establishment of Disturbance Zone or Zone of Influence—Disturbance zones or zones of influence (ZOI) are the areas in which SPLs equal or exceed 160 dB rms for impact driving and 120 dB rms for vibratory driving. Disturbance zones provide utility for monitoring by establishing monitoring protocols for areas adjacent to the shutdown zones. Monitoring of disturbance zones enables observers to be aware of and communicate the presence of marine mammals in the project area but outside the shutdown zone and thus prepare for potential shutdowns of activity. However, the primary purpose of disturbance zone monitoring is for documenting incidents of Level B harassment; disturbance zone monitoring is discussed in greater detail later (see "Proposed Monitoring and Reporting"). Nominal radial distances for disturbance zones are shown in Table 5. We discuss monitoring objectives and protocols in greater depth in "Proposed Monitoring and Reporting."

Soft Start—The use of a soft-start procedure is believed to provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full capacity. Soft-start techniques for impact pile driving will be conducted in accordance with the Anchorage Fish and Wildlife Field Office (AFWFO, 2012) Observer Protocols. For impact pile driving, contractors will be required to provide an initial set of strikes from the hammer at 40 percent energy, each strike followed by no less than a 30-second waiting period. This procedure will be conducted a total of three times before impact pile driving begins.

Mitigation Conclusions

We have carefully evaluated ADOT&PF's proposed mitigation measures and considered their effectiveness in past implementation to determine whether they are likely to effect the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another: (1) The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals, (2) the proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and (3) the practicability of the measure for applicant implementation.

Any mitigation measure(s) we prescribe should be able to accomplish, have a reasonable likelihood of accomplishing (based on current science), or contribute to the accomplishment of one or more of the general goals listed below:

(1) Avoidance or minimization of injury or death of marine mammals wherever possible (goals 2, 3, and 4 may contribute to this goal).

(2) A reduction in the number (total number or number at biologically important time or location) of individual marine mammals exposed to stimuli expected to result in incidental take (this goal may contribute to 1 above).

(3) A reduction in the number (total number or number at biologically important time or location) of times any individual marine mammal would be exposed to stimuli expected to result in incidental take (this goal may contribute to 1 above).

(4) A reduction in the intensity of exposure to stimuli expected to result in incidental take (this goal may contribute to 1 above).

(5) Avoidance or minimization of adverse effects to marine mammal habitat, paying particular attention to the prey base, blockage or limitation of passage to or from biologically important areas, permanent destruction of habitat, or temporary disturbance of habitat during a biologically important time.

(6) For monitoring directly related to mitigation, an increase in the probability of detecting marine mammals, thus allowing for more effective implementation of the mitigation.

Based on our evaluation of ADOT&PF's proposed measures, including information from monitoring of implementation of mitigation measures very similar to those described here under previous IHAs from other marine construction projects, we have determined that the proposed mitigation measures provide the means of effecting the least practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth "requirements pertaining to the monitoring and reporting of such taking." The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for incidental take authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. ADOT&PF submitted a marine mammal monitoring plan as part of the IHA application. It can be found in Appendix B of the Application. The plan may be modified or supplemented based on comments or new information received from the public during the public comment period.

Any monitoring requirement we prescribe should improve our understanding of one or more of the following:

- Occurrence of marine mammal species in action area (*e.g.,*presence, abundance, distribution, density).
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) Affected species (*e.g.,* life history, dive patterns); (3) Co-occurrence of marine mammal species with the action; or (4) Biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas).
- Individual responses to acute stressors, or impacts of chronic exposures (behavioral or physiological).
- How anticipated responses to stressors impact either: (1) Long-term fitness and survival of an individual; or (2) Population, species, or stock.
- Effects on marine mammal habitat and resultant impacts to marine mammals.
- Mitigation and monitoring effectiveness.

Proposed Monitoring Measures

Monitoring Protocols—Monitoring will be conducted by qualified marine mammal observers (MMO), who are trained biologists, with the following minimum qualifications:

(a) Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the water's surface with ability to estimate target size and distance. Use of spotting scopes and binoculars may be necessary to correctly identify the target.

(b) Experience and ability to conduct field observations and collect data according to assigned protocols (this may include academic experience).

(c) Experience or training in the field identification of marine mammals (cetaceans and pinnipeds).

(d) Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations.

(e) Writing skills sufficient to prepare a report of observations that would include such information as the number and type of marine mammals observed; the behavior of marine mammals in the project area during construction; dates and times when observations were conducted; dates and times when in-water construction activities were conducted; dates and times when marine mammals were present at or within the defined disturbance or injury zones; dates and times when in-water construction activities were suspended to avoid injury from construction noise; etc.

(f) Ability to communicate orally, by radio or in person, with project personnel to provide real time information on marine mammals observed in the area as necessary.

In order to effectively monitor the pile driving monitoring zones, the MMO will be positioned at the best practical vantage point. The monitoring position may vary based on pile driving activities and the locations of the piles and driving equipment. These may include the catwalk at the ferry terminal, the contractor barge, or another location deemed to be more advantageous. The monitoring location will be identified with the following characteristics: 1. Unobstructed view of pile being driven; 2. Unobstructed view of all water within a 1.9 km (vibratory driving) and 1.6 km (impact driving) radius of each pile; 3. Clear view of pile-driving operator or construction foreman in the event of radio failure; and 4. Safe distance from pile driving activities in the construction area.

A single MMO will be situated on the Ferry Terminal to monitor the appropriate injury and behavioral disturbance zones during all pile driving activities. Because the action area for vibratory driving disturbance extends for 1.9 kilometers from the Gustavus Ferry Terminal into Icy Strait/Passage, it would be difficult to monitor this area effectively with only terminal-based MMOs. Due to potentially severe and highly unpredictable weather conditions, ADOT&PF has concluded that the use of Pleasant Island-based, mainland-based, or vessel-based MMOs would be infeasible and, in many circumstances, unsafe. However, when possible, ADOT&PF will augment land-based monitoring with information from boats in Icy Strait/Passage. Specifically, the MMO will coordinate with the NPS and whale-watching charters for recent observations of marine mammals within Icy Strait/Passage. This will help inform the MMO of marine mammals in the area. NPS and whale-watching charters could also inform monitoring personnel of any marine mammals seen approaching the disturbance zone. The MMO will conduct telephone checks with NPS and whale-watching charters to monitor the locations of humpback whales and Steller sea lions, which are listed under the Endangered Species Act, within Icy Strait/Passage. Checks will begin three days before pile-driving operations to ascertain the location and movements of these listed species in relation to the disturbance zones. Once construction has begun, checks will be made in the evening after the completion of pile driving activities, in preparation of the next day's monitoring. Use of the organizations identified above to augment monitoring efforts will depend on their observation schedules and locations within the Glacier Bay region. It is expected that these organizations will only be active in May and September during the pile-driving season.

The following additional measures apply to visual monitoring:

- Monitoring will begin 30 minutes prior to pile driving. This will ensure that all marine mammals in the monitoring zone are documented and that no marine mammals are present in the injury zone;
- If a marine mammal comes within or approaches the shutdown zone, such operations shall cease. Pile driving will only commence once observers have declared the shutdown zone clear of marine mammals. Their behavior will be monitored and documented. The shutdown zone may only be declared clear, and pile driving started, when the entire shutdown zone is visible (*i.e.*, when not obscured by dark, rain, fog, etc.);
- When a marine mammal is observed, its location will be determined using a rangefinder to verify distance and a GPS or compass to verify heading;
- If any cetaceans or pinnipeds are observed approaching injury zones, impact pile-driving activities will be immediately halted. The MMO will immediately radio to alert the contractor and raise a red flag, requiring an immediate "all-stop." Impact pile-driving activities will resume when the animal is no longer proximal to the injury zone or 30 minutes have passed without re-sighting the animal near the zone. The observer will continue to monitor the animal until it has left the larger disturbance zones;
- The MMOs will record any cetacean or pinniped present in the disturbance zone;
- MMOs will record all harbor seals present in the in-air disturbance zone. This applies to animals that are hauled out and those that have surfaced while swimming;
- At the end of the pile-driving day, post-construction monitoring will be conducted for 30 minutes beyond the cessation of pile driving;
- If any cetaceans or pinnipeds are observed approaching the 10-meter exclusion zone, heavy equipment activities will be immediately halted. The observer will immediately radio to alert the contractor and raise a red flag, requiring an immediate "all-stop." Observers will continue to monitor the animal after it has left the injury zone, if visible;
- If any marine mammal species are encountered during activities that are not listed in Table 1 for authorized taking and are likely to be exposed to SPLs greater than or equal to 160 dB re 1 μPa (rms) for impact driving and 120 dB re 1 μPa (rms), then the Holder of this Authorization must stop pile driving activities and report observations to NMFS' Office of Protected Resources;
- If waters exceed a sea-state which restricts the observers' ability to make observations within the marine mammal shutdown zone (*e.g.*, excessive wind or fog), pile installation will cease. Pile driving will not be initiated until the entire shutdown zone is visible;
- Work would occur only during daylight hours, when visual monitoring of marine mammals can be conducted; and
- Pile driving in September or May will end by approximately 5:00 p.m. local time to avoid the late afternoon period when most fishing charters return to the public dock adjacent to the Ferry Terminal. This is also the time of

day when most sea lions are attracted to the Ferry Terminal, due to fish processing activities; therefore, shutting down construction operations at this time will help to avoid take of sea lions.

Data Collection

Observers are required to use approved data forms. Among other pieces of information, ADOT&PF will record detailed information about any implementation of shutdowns, including the distance of animals to the pile and description of specific actions that ensued and resulting behavior of the animal, if any. In addition, the ADOT&PF will attempt to distinguish between the number of individual animals taken and the number of incidents of take. At a minimum, the following information will be collected on the sighting forms:

- Date and time that monitored activity begins or ends;
- Construction activities occurring during each observation period;
- Weather parameters (*e.g.*, percent cover, visibility);
- Water conditions (*e.g.*, sea state, tide state);
- Species, numbers, and, if possible, sex and age class of marine mammals;
- Description of any observable marine mammal behavior patterns, including bearing and direction of travel and distance from pile driving activity;
- Distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point;
- Locations of all marine mammal observations; and
- Other human activity in the area.

Reporting

ADOT&PF will notify NMFS prior to the initiation of the pile driving activities and will provide NMFS with a draft monitoring report within 90 days of the conclusion of the proposed construction work. This report will detail the monitoring protocol, summarize the data recorded during monitoring, and estimate the number of marine mammals that may have been harassed. If no comments are received from NMFS within 30 days of submission of the draft final report, the draft final report will constitute the final report. If comments are received, a final report must be submitted within 30 days after receipt of comments.

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines "harassment" as: ". . .any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment]."

All anticipated takes would be by Level B harassment resulting from vibratory and impact pile driving and involving temporary changes in behavior. The proposed mitigation and monitoring measures are expected to minimize the possibility of injurious or lethal takes such that take by Level A harassment, serious injury, or mortality is considered discountable. However, it is unlikely that injurious or lethal takes would occur even in the absence of the planned mitigation and monitoring measures.

Given the many uncertainties in predicting the quantity and types of impacts of sound on marine mammals, it is common practice to estimate how many animals are likely to be present within a particular distance of a given activity, or exposed to a particular level of sound.

ADOT&PF has requested authorization for the incidental taking of small numbers of marine mammals near the Gustavus Ferry Terminal that may result from impact pile driving, vibratory pile driving and vibratory pile removal. In order to estimate the potential incidents of take that may occur incidental to the specified activity, we must first estimate the extent of the sound field that may be produced by the activity and then consider in combination with information about marine mammal density or abundance in the project area. We first provide information on applicable sound thresholds for determining effects to marine mammals before describing the information used in estimating the sound fields, the available marine mammal density or abundance information, and the method of estimating potential incidences of take.

Sound Thresholds

We use the generic sound exposure thresholds shown in Table 4 to determine when an activity that produces underwater sound might result in impacts to a marine mammal such that a take by harassment might occur.

TABLE 4—UNDERWATER INJURY AND DISTURBANCE THRESHOLD DECIBEL LEVELS FOR MARINE MAMMALS

Criterion	Criterion definition	Threshold*
Level A harassment	PTS (injury) conservatively based on TTS**	190 dB rms for pinnipeds. 180 dB rms for cetaceans.
Level B harassment	Behavioral disruption for impulse noise (*e.g.*, impact pile driving)	160 dB rms.
Level B harassment	Behavioral disruption for non-pulse noise (*e.g.*, vibratory pile driving, drilling).	120 dB rms.

* All decibel levels referenced to 1 μPa. Note all thresholds are based off root mean square (rms) levels.
** PTS=Permanent Threshold Shift; TTS=Temporary Threshold Shift.

Distance to Sound Thresholds

The sound field in the project area is the existing ambient noise plus additional construction noise from the proposed project. The primary components of the project expected to affect marine mammals are the sounds generated by impact pile driving, vibratory pile driving, and vibratory pile removal.

In order to calculate the Level A and Level B sound thresholds, ADOT&PF used acoustic monitoring data for this project that had been collected at the Kake Ferry Terminal, located approximately 115 miles south of the project area (MacGillvray *et al.*, 2015; Appendix A). ADOT&PF provided a comprehensive analysis describing how the Kake Ferry Terminal data provides a more accurate representation of underwater noise than the California-based dataset that NMFS usually recommends.

The Gustavus Ferry Terminal improvement project proposes to use

24- and 30-inch-diameter steel piles for most project support components. According to data collected from the Kake Ferry Terminal (MacGillvray *et al.*, 2015; Appendix A) and WSDOT (Laughlin 2010; WSDOT 2014), piles of this size generate similar levels of waterborne noise. The sound levels selected to calculate impact zones are as follows:

- Waterborne noise: 193.2 dB rms for impact driving and 154.3 dB rms for vibratory driving

The formula below is used to calculate underwater sound propagation. Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater TL is:

$TL = B * \log_{10} (R_1/R_2)$

Where:

TL = transmission loss in dB
B = wave mode coefficient; for practical spreading equals 15
R_1 = the distance of the modeled SPL from the driven pile, and
R_2 = the distance from the driven pile of the initial measurement.

NMFS typically recommends a default practical spreading loss of 15 dB per tenfold increase in distance. ADOT&PF analyzed the available underwater acoustic data utilizing the practical spreading loss model.

The practical spreading loss model estimates small injury zones for whales (76 m) and pinnipeds (16 m) for pulsed sound generated by piles driven by an impact pile driver within the project area. The disturbance zone for impact pile driving is larger, at approximately 1.6 km from the driven pile for all marine mammals. The disturbance zone for continuous noise generated by a vibratory hammer is similar, predicted to extend for 1.9 km from the pile to an ambient background level of 120 dB. For airborne sound, the Level B disturbance threshold is calculated at 163 m for harbor seals and 51 m for other pinnipeds during impact driving and 36 m for harbor seals during vibratory driving. The selected sound level of 97 dB for vibratory driving is below the 100 dB disturbance threshold for other pinnipeds, so there is no disturbance zone for other pinniped species.

TABLE 5—IMPACT ZONES OF MARINE MAMMALS

Pile driver type	Distance to criterion (meters)			
	Waterborne noise			
	Marine mammal disturbance (160 dB)/Level B	Cetacean injury (180 dB)/Level A	Pinniped injury (190 dB)/Level A	Continuous noise disturbance (120 dB)/Level B
Impact	1,634	76	16	
Vibratory				1,935

Note that the actual area ensonified by pile driving activities is significantly constrained by local topography relative to the total threshold radius. The actual ensonified area was determined using a straight line-of-sight projection from the anticipated pile driving locations. Distances to the underwater sound isopleths for Level B and Level A are illustrated respectively in Figure 2 and Figure 3 in the Application.

The method used for calculating potential exposures to impact and vibratory pile driving noise for each threshold uses local marine mammal data sets and data from IHA estimates on similar projects with similar actions. All estimates are conservative and include the following assumptions:

- All pilings installed at each site would have an underwater noise disturbance equal to the piling that causes the greatest noise disturbance (*i.e.*, the piling furthest from shore) installed with the method that has the largest ZOI. The largest underwater disturbance ZOI would be produced by vibratory driving steel and timber piles. The ZOIs for each threshold are not spherical and are truncated by land masses on either side of the channel which would dissipate sound pressure waves; and
- Exposures were based on estimated work days. Between 16 and 50 work days of pile driving and removal will be required for the proposed project. NMFS will assume that a full 50 days are required to complete pile driving and removal activities.

The calculation for marine mammal exposures, except for Dall's porpoise and killer whales, was estimated using the following:

Exposure estimate = N (number of animals exposed above disturbance threshold) × no. of days of pile driving/removal activity.

The methods for the calculation of exposures for Dall's porpoise and killer whales is described under those respective species below.

Harbor Seal

There are no documented haulout sites for harbor seals in the vicinity of the project. The nearest haulouts, rookeries, and pupping grounds occur in Glacier Bay over 20 miles from the ferry terminal. However, occasionally an individual will haul out on rocks on the north side of Pleasant Island (Stephen Vanderhoff, SWE, personal communication). A recent study of post-breeding harbor seal migrations from Glacier Bay demonstrates that some harbor seals traveled extensively beyond the boundaries of Glacier Bay during the post-breeding season (Womble and Gende 2013). Strong fidelity of individuals for haulout sites during the breeding season was documented in this study as well.

Harbor seals have declined dramatically in Glacier Bay region over the past few decades which may be a reason why there are few observations at the Gustavus Ferry Terminal. Sightings of harbor seals around the ferry terminal used to be more common (Stephen Vanderhoff, SWE, personal communication). NPS has documented one harbor seal observation near the terminal. It is estimated that less than 10 individuals are seen near the ferry dock during charter boat operations from mid- to late-May through September (Tod Sebens, CSE, Stephen Vanderhoff, SWE, Bruce Kruger, ADF&G, personal communication). Harbor seals are also documented in Icy Passage in the winter and early spring (Womble and Gende 2013).

For this analysis, we take a conservative estimate and assume that four harbor seals could be present on any day of pile driving regardless of when the pile driving is conducted (Spring and Fall 2017). Two seals would be subject would be exposed to underwater noise. Therefore, it is estimated that the following number of harbor seals may be present in the disturbance zone:

- *Underwater exposure estimate:* 4 animals × 50 days of pile activity = 200.

NMFS proposes authorization for 200 Level B acoustical harassment takes of harbor seals. It is likely that one or more animals will be taken on repeated or subsequent days. Therefore, the number of individual animals taken will likely be less than 200.

Steller Sea lion

There are numerous Steller sea lion haulouts in Icy Strait but none occurring in Icy Passage (Mathews *et al.,* 2011; Tod Sebens, CSE, Stephen Vanderhoff, SWE, Janet Neilson, NPS, personal communication). The nearest Steller sea lion haulout sites are located on Black Rock on the south side of Pleasant Island and Point Carolus west across the strait from Point Gustavus (Mathews *et al.,* 2011). Both haulouts are over 16 km from the Gustavus ferry terminal.

Steller sea lions are common in the ferry terminal area during the charter fishing season (May to September) and are known to haul out on the public dock (Tod Sebens, CSE, Stephen Vanderhoff, SWE, Janet Neilson, NPS, personal communication Bruce Kruger, ADF&G, personal communication). During the charter fishing season, Steller sea lions begin arriving at the ferry terminal as early as 2:00 p.m. local time, reaching maximum abundance when the charter boats return at approximately 5:00 p.m. local time. The sea lions forage on the carcasses of the sport fish catch and then vacate the area. For the sake of our analysis we propose at least 10 animals will be present every day during charter fishing season. Outside of the charter fishing season, it is assumed that two Steller sea lions may transit in front of the ferry terminal to and from foraging grounds.

For the purpose of our analysis we conservatively estimate that two Steller sea lions will transit within the disturbance zones each day during the months of October and November of 2017 as well as March and April of 2018. We estimate, conservatively, that up to 10 individuals may be present each day in the months of September 2017 and May 2018 during the charter fishing season.

We also assume that 33 total combined days of pile driving/removal will occur in October and November, 2017 as well as in March and April, 2018. Seventeen combined driving days will occur in September, 2017 and May, 2018. Using these estimates we calculate the following number of Steller sea lions may be present in the disturbance zone:

- October 2017, November 2017, March 2018 and April 2018 underwater exposure estimate: 2 animals × 33 days of pile activity = 66
- September 2017 and May 2018 underwater exposure estimate: 10 animals × 17 days of pile activity = 170

The underwater take estimate for March through November is 236 animals. NMFS proposes authorization for 236 Level B acoustical harassment takes of Steller sea lions. Note that a small number of Steller sea lions (up to five) may have become habituated to human activity and, therefore, it is highly likely that there will be numerous repeated takes of these same animals. (Kruger, ADF&G, personal communication).

Dall's Porpoise

Dall's porpoise are documented in Icy Strait but not Icy Passage. Dahlheim *et al.,* (2009) found Dall's porpoise throughout Southeast Alaska, with concentrations of animals consistently found in Icy Strait, Lynn Canal, Stephens Passage, upper Chatham Strait, Frederick Sound, and Clarence Strait. It is estimated that there are anywhere from four to 12 sightings of Dall's porpoise in Icy Strait per season during the May through September whale watching charter months (Tod Sebens, CSE, Stephen Vanderhoff, SWE, personal communication). NPS documented seven sightings in Icy Strait since 1993 in September, October, November, April, and May. Six of the seven sightings are of pods with less than 10 individuals. The mean group size of Dall's porpoise in Southeast Alaska is estimated at three individuals (Dahlheim *et al.,* 2009).

Based on observations of local marine mammal specialists, Dall's porpoise are uncommon in Icy Passage. However, they do occur in Icy Strait and could potentially transit through the disturbance zone. For this analysis, we take the maximum number of 12 sightings per season between May and September, which equates to 2.4 sightings per month. Using this number it is estimated that the following number of Dall's porpoise may be present in the disturbance zone:

- Underwater exposure estimate: 2.4 group sightings/month × 3 animals/group × 6 months of pile activity = 43.2

NMFS proposes authorizing the Level B take of 43 Dall's porpoise.

Harbor Porpoise

Harbor porpoise are common in Icy Strait. Concentrations of harbor porpoise were consistently found in varying habitats surrounding Zarembo Island and Wrangell Island, and throughout the Glacier Bay and Icy Strait regions (Dahlheim *et al.,* 2009). These concentrations persisted throughout the three seasons sampled. Dahlheim (2015) indicated that 332 resident harbor porpoises occur in the Icy Strait area, though the population has been declining across Southeast Alaska since the early 1990's (Dahlheim *et al.,* 2012). During a 2014 survey, Barlow *et al.* (in press) observed 462 harbor porpoises in the Glacier Bay and Icy Strait area during a three-month summer survey period. It is estimated that harbor porpoise are observed on at least 75 percent of whale watch excursions (75 of 100 days) during the May through September months (Tod Sebens, CSE, Stephen Vanderhoff, SWE, personal communication). While NPS documented numerous sightings in Icy Strait since 1993 in September, October, November, April, and May, none were observed in Icy Passage. The mean group size of harbor porpoise in Southeast Alaska is estimated at two individuals (Dahlheim *et al.,* 2009).

Harbor porpoise could potentially transit through the disturbance zone during pile driving activity. For this analysis we take a conservative estimate and assume that four harbor porpoise (two pods of two per day) could be present on any of the 50 days of pile driving. Using this number it is estimated that the following number of harbor porpoise may be present in the disturbance zone:

Underwater exposure estimate:

- 4 animals × 50 days of pile activity = 200

NMFS is proposing authorization for 200 Level B acoustical harassment takes of harbor porpoise.

Humpback Whale

From May to September, humpback whales congregate and forage in nearby Glacier Bay and in Icy Strait. Since 1985, the NPS has been monitoring humpback whales in both Glacier Bay National Park and Icy Strait and publishing annual reports (*http://www.nps.gov/glba/naturescience/whale_acoustic_reports.htm*). The NPS typically surveys Icy Strait, located south of Icy Passage, once a week between June 1 and August 31, with most survey effort focused in the area east of Point Gustavus and Pleasant Island (Figure 3). Several Icy Strait surveys included waters around

Pleasant Island, the closest island to the Gustavus Ferry Terminal. Because the NPS is most interested in whales within Glacier Bay and areas where vessel management is a concern, their monitoring data do not represent a true distribution of whales. Their survey locations are also dependent on where the whales are actually distributed (Neilson *et al.,* 2014).

In 2013, 237 humpback whales were documented in Icy Strait during the NPS monitoring period; this was a 14 percent increase over the previous high count of 177 whales in 2012 (Neilson *et al.,* 2014). In 2014, a 39 percent decrease in area abundance was observed (124 whales), which may have been caused by increased turbidity resulting from seismic generated marine landslides (Neilson *et al.,* 2015). The majority of whales observed in Icy Strait in 2013 and 2014 were recorded in the area between the mouth of Glacier Bay and Point Adolphus; there were no whales observed between Pleasant Island and the Gustavus Ferry Terminal (the waterbody known as Icy Passage). While this does not mean that no whales were present between the island and ferry terminal at any time, it does suggest that the number of individual whales present in Icy Passage is relatively low and occurrence is infrequent. In other years, a number of humpback whales have been observed to the south and west of Pleasant Island (Neilson *et al.,* 2014; Figures 4 through 6). The lack of whale observations between Pleasant Island and the ferry terminal likely reflects the fact that Icy Passage is relatively shallow and muddy; for this reason NPS does not consider it a whale "hot spot" (C. Gabriele, NPS, personal communication).

Based on these observations humpback whales appear to be common in Icy Strait and are occasionally seen in Icy Passage. However, NPS believes that whale abundance decreases substantially in September through November and March through April, but has limited data for these periods. For this analysis, we take a conservative estimate and assume that two humpback whales could be present in the disturbance zone on any day of the 50 days of pile driving. Using this number it is estimated that the following number of humpback whales may be present in the disturbance zone:

Underwater exposure estimate:

- 2 animals × 50 days of pile activity = 100

NMFS is proposing authorization for 100 Level B acoustical harassment takes of humpback whales.

Killer whale

Based on observations of local marine mammal specialists, the probability of killer whales occurring in Icy Passage is low. However, they do occur in Icy Strait and could potentially transit through the disturbance zone in Icy Passage. Since there is no density information available for killer whales in this area, we assumed a pod size of 27 for resident and six for transient killer whales, based on an average of group sizes observed during surveys in Spring and Fall in Southeast Alaska between 1991 and 2007 (Dalheim *et al.,* 2008). We also assumed that a pod of resident (27) or transient (6) killer whales may occur in the Level B disturbance zone twice during the course of the project. Therefore, to account for the potential for two resident (54 total) and two transient pods (12 total) to occur in the disturbance zone during the course of the project, ADOT&PF is requesting authorization for 66 Level B acoustical harassment takes of killer whales.

Minke Whale

Based on observations of local marine mammal specialists, the probability of minke whales occurring in Icy Passage is low. However, they have been documented in Icy Strait and could potentially transit through the disturbance zone. For this analysis, we take a conservative estimate and assume that one minke whale could be present on any one day during the 50 days of pile driving. Using this number it is estimated that the following number of minke whales may be present in the disturbance zone:

Underwater exposure estimate:

- 1 animal × 50 days of pile activity = 50

NMFS is therefore proposing authorization for 50 Level B acoustical harassment takes of minke whales.

Analyses and Preliminary Determinations

Negligible Impact Analysis

Negligible impact is "an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival" (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of Level B harassment takes, alone, is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be "taken" through behavioral harassment, NMFS must consider other factors, such as the likely nature of any responses (their intensity, duration, etc.), the context of any responses (critical reproductive time or location, migration, etc.), as well as the number and nature of estimated Level A harassment takes, the number of estimated mortalities, effects on habitat, and the status of the species.

To avoid repetition, the discussion of our analyses applies to all the species listed in Table 1. There is little information about the nature of severity of the impacts or the size, status, or structure of any species or stock that would lead to a different analysis for this activity.

Pile driving and pile extraction activities associated with the Gustavus Ferry Terminal improvements project, as outlined previously, have the potential to disturb or displace marine mammals. Specifically, the specified activities may result in Level B harassment (behavioral disturbance) for all species authorized for take, from underwater sound generated from pile driving and removal. Potential takes could occur if individuals of these species are present in the ensonified zone when pile driving or drilling is under way.

The takes from Level B harassment will be due to potential behavioral disturbance and potential TTS. Serious injury or death is unlikely for all authorized species and injury is unlikely for these species, as ADOT&PF will enact several required mitigation measures. Soft start techniques will be employed during pile driving operations to allow marine mammals to vacate the area prior to commencement of full power driving. ADOT&PF will establish and monitor shutdown zones for authorized species, which will prevent injury to these species. ADOT&PF will also record all occurrences of marine mammals and any behavior or behavioral reactions observed, any observed incidents of behavioral harassment, and any required shutdowns, and will submit a report upon completion of the project. We have determined that the required mitigation measures are sufficient to reduce the effects of the specified activities to the level of effecting the least practicable adverse impact upon the affected species, as required by the MMPA.

The ADOT&PF's proposed activities are localized and of short duration. The entire project area is limited to the Gustavus Ferry Terminal area and its immediate surroundings. Specifically, the use of impact driving will be limited to an estimated maximum of 57 hours over the course of 16 to 50 days of construction. Total vibratory pile driving time is estimated at 114 hours over the same period. While impact driving does have the potential to cause injury to marine mammals, mitigation in the form of shutdown zones should eliminate exposure to Level A thresholds. Vibratory driving does not have significant potential to cause injury to marine mammals due to the relatively low source levels produced and the lack of potentially injurious source characteristics. Additionally, no important feeding and/or reproductive areas for marine mammals are known to be within the ensonified area during the construction time frame.

The project also is not expected to have significant adverse effects on affected marine mammals' habitat. The project activities would not modify existing marine mammal habitat. The activities may cause some fish to leave the area of disturbance, thus temporarily impacting marine mammals' foraging opportunities in a limited portion of the foraging range; but, because of the short duration of the activities and the relatively small area of the habitat that may be affected, the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences.

Effects on individuals that are taken by Level B harassment, on the basis of reports in the literature as well as monitoring from other similar activities, will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring) (*e.g.*, Thorson and Reyff, 2006; Lerma, 2014). Most likely, individuals will simply move away from the sound source and be temporarily displaced from the areas of pile driving, although even this reaction has been observed primarily only in association with impact pile driving. In response to vibratory driving, pinnipeds (which may become somewhat habituated to human activity in industrial or urban waterways) have been observed to orient towards and sometimes move towards the sound. The pile extraction and driving activities analyzed here are similar to, or less impactful than, numerous construction activities conducted in other similar locations, which have taken place with no reported serious injuries or mortality to marine mammals, and no known long-term adverse consequences from behavioral harassment. Repeated exposures of individuals to levels of sound that may cause Level B harassment are unlikely to result in hearing impairment or to significantly disrupt foraging behavior. Thus, even repeated Level B harassment of some small subset of the overall stock is unlikely to result in any significant realized decrease in fitness for the affected individuals, and thus would not result in any adverse impact to the stock as a whole.

In summary, this negligible impact analysis is founded on the following factors: (1) The possibility of serious injury or mortality to authorized species may reasonably be considered discountable; (2) the anticipated incidents of Level B harassment consist of, at worst, temporary modifications in behavior and; (3) the presumed efficacy of the planned mitigation measures in reducing the effects of the specified activity to the level of effecting the least practicable adverse impact upon the affected species. In combination, we believe that these factors, as well as the available body of evidence from other similar activities, demonstrate that the potential effects of the specified activity will have only short-term effects on individuals. The specified activity is not expected to impact rates of recruitment or survival and will therefore not result in population-level impacts.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the planned monitoring and mitigation measures, NMFS finds that the total marine mammal take from ADOT&PF's Gustavus Ferry terminal improvement project will have a negligible impact on the affected marine mammal species or stocks.

TABLE 6—ESTIMATED NUMBER OF EXPOSURES AND PERCENTAGE OF STOCKS THAT MAY BE SUBJECT TO LEVEL B HARASSMENT

Species	Proposed authorized takes	Stock(s) abundance estimate	Percentage of total stock
Harbor Seal	200	7,210	2.8.
Steller Sea Lion	236	49,497 (western stock in AK)	0.48.
		60,131 (eastern stock)	0.39.
Dall's Porpoise	43	Unknown	Unknown.
Harbor Porpoise	200	11,146	1.7.
Humpback Whale	100	10,252	0.98.
Killer whale	66	261 (Northern resident)	25.3.
		587 (Gulf of Alaska transient)	11.2.
		243 (West Coast transient)	27.1.
Minke Whale	50	Unknown	Unknown.

Small Numbers Analysis

Table 6 demonstrates the number of animals that could be exposed to received noise levels that could cause Level B behavioral harassment for the proposed work at the Gustavus Ferry Terminal project. The analyses provided above represents between 0.39–27.1 percent of the populations of these stocks that could be affected by harassment, except for Minke whales and Dall's porpoise, since their population numbers are unknown. While the proposed West Coast transient and Northern resident killer whale takes and percentages of stock affected appears high (27.1 percent and 25.3 percent), in reality only 66 transient killer whale individuals are not likely to be harassed. Instead, it is more likely that there will be multiple takes of a smaller number of individuals. Both the West coast transient stock and the Northern Resident stock range from southeastern Alaska, through British Columbia, and into northern Washington. It is unlikely that such a large portion of either stock with ranges of this size would be concentrated in and around Icy Passage.

Furthermore, though there is not a current abundance estimate, the proposed take of 43 Dall's porpoise and

50 Minke whale are also considered small numbers. Population data on these species is dated. Surveys conducted between 1987 and 1991 put the population of the Alaska stock of Dall's porpoise at between 83,400 and 417,000 (Allen and Angliss, 2012). As such, the 14 proposed authorized takes represent <0.01 percent of the population. A visual survey for cetaceans was conducted in the central-eastern Bering Sea in July-August 1999, and in the southeastern Bering Sea in 2000. Results of the surveys in 1999 and 2000 provide provisional abundance estimates of 810 and 1,003 minke whales in the central-eastern and southeastern Bering Sea, respectively (Moore *et al.*, 2002). Additionally, line-transect surveys were conducted in shelf and nearshore waters in 2001–2003 from the Kenai Fjords in the Gulf of Alaska to the central Aleutian Islands. Minke whale abundance was estimated to be 1,233 for this area (Zerbini *et al.*, 2006). However, these estimates cannot be used as an estimate of the entire Alaska stock of minke whales because only a portion of the stock's range was surveyed. (Allen and Anglis 2012). Clearly, 50 authorized takes should be considered a small number, as it constitutes only 6.1 percent of the smallest abundance estimate generated during the surveys just described and each of these surveys represented only a portion of the minke whale range.

Note that the numbers of animals authorized to be taken for all species, with the exception of resident killer whales, would be considered small relative to the relevant stocks or populations even if each estimated taking occurred to a new individual—an extremely unlikely scenario.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures, which are expected to reduce the number of marine mammals potentially affected by the proposed action, NMFS finds that small numbers of marine mammals will be taken relative to the populations of the affected species or stocks.

Impact on Availability of Affected Species for Taking for Subsistence Use

The proposed Gustavus Ferry Terminal Improvements project will occur near but not overlap the subsistence area used by the villages of Hoonah and Angoon (Wolfe *et al.*, 2013). Harbor seals and Steller sea lions are available for subsistence harvest in this area (Wolfe *et al.*, 2013). There are no harvest quotas for other non-listed marine mammals found there. The Alaska Department of Fish and Game (Wolfe *et al.*, 2013) has regularly conducted surveys of harbor seal and Steller sea lion subsistence harvest in Alaska. Since proposed work at the Gustavus Ferry Terminal will only cause temporary, nonlethal disturbance of marine mammals, we anticipate no impacts to subsistence harvest of marine mammals in the region.

Endangered Species Act (ESA)

There are two marine mammal species that are listed as endangered under the ESA with confirmed or possible occurrence in the study area: humpback whale and Steller sea lion (Western DPS). NMFS' Permits and Conservation Division has initiated consultation with NMFS' Protected Resources Division under section 7 of the ESA on the issuance of an IHA to ADOT&PF under section 101(a)(5)(D) of the MMPA for this activity. Consultation will be concluded prior to a determination on the issuance of an IHA.

National Environmental Policy Act (NEPA)

NMFS is preparing an EA in accordance with the NEPA and will consider comments submitted in response to this notice as part of that process. The draft EA will be posted at *http://www.nmfs.noaa.gov/pr/permits/incidental/construction.htm* once it is finalized.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to ADOT&PF for reconstructing the existing Gustavus Ferry Terminal located in Gustavus, Alaska, Alaska, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. The proposed IHA language is provided next.

1. This Incidental Harassment Authorization (IHA) is valid from September 1, 2017 through August 31, 2018.

2. This Authorization is valid only for in-water construction work associated with the reconstruction of the existing Gustavus Ferry Terminal located in Gustavus, Alaska.

3. General Conditions.

(a) A copy of this IHA must be in the possession of the Alaska Department of Transportation & Public Facilities (ADOT&PF), its designees, and work crew personnel operating under the authority of this IHA.

(b) The species authorized for taking are harbor seal (*Phoca vitulina*), Steller sea lion (*Eumatopius jubatus*), Dall's porpoise (*Phocoenoides dalli*), harbor porpoise (*Phocoena phocoena*), humpback whale (*Megaptera novaeangliae*), killer whale (*Orcinus orca*), and minke whale (*Balaenoptera acutorostrata*).

(c) The taking, by Level B harassment only, is limited to the species listed in condition 3(b).

(d) The taking by injury (Level A harassment), serious injury, or death of any of the species listed in condition 3(b) of the Authorization or any taking of any other species of marine mammal is prohibited and may result in the modification, suspension, or revocation of this IHA.

4. Mitigation Measures.

The holder of this Authorization is required to implement the following mitigation measures:

(a) Time Restriction: For all in-water pile driving activities, ADOT&PF shall operate only during daylight hours when visual monitoring of marine mammals can be conducted;

(b) To limit the amount of waterborne noise, a vibratory hammer will be used for initial driving, followed by an impact hammer to proof the pile to required load-bearing capacity;

(c) Establishment of Level B Harassment Zones of Influence (ZOIs):

(i) Before the commencement of in-water pile driving activities, ADOT&PF shall establish Level B behavioral harassment ZOIs where received underwater sound pressure levels (SPLs) are higher than 160 dB (rms) and 120 dB (rms) re 1 μPa for impulse noise sources (impact pile driving) and non-pulse sources (vibratory hammer), respectively; and

(ii) The ZOIs delineate where Level B harassment would occur. For impact driving, the area within the Level B harassment threshold is between approximately 76 m and 1.6 km. For vibratory driving, the level B harassment area is between 10 m and 1.9 km.

(d) Establishment of shutdown zone—Implement a minimum shutdown zone around the pile of 76 m radius during impact pile driving and 10 m during vibratory driving activities. If a marine mammal comes within or approaches the shutdown zone, such operations shall cease.

(e) Use of Soft-start:

(i) The project will utilize soft start techniques for impact pile driving. Contractors shall be required to provide an initial set of three strikes from the impact hammer at 40 percent reduced energy, followed by a thirty-second waiting period, then two subsequent three strike sets. Soft start will be required at the beginning of each day's pile driving work and at any time following a cessation of pile driving of thirty minutes or longer (specific to either vibratory or impact driving); and

(ii) Whenever there has been downtime of 20 minutes or more without vibratory or impact driving, the contractor will initiate the driving with soft-start procedures described above.

(f) Standard mitigation measures:

(i)(e) ADOT&PF shall conduct briefings between construction supervisors and crews, marine mammal monitoring team, and staff prior to the start of all in-water pile driving, and when new personnel join the work, in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures; and

(ii) For in-water heavy machinery work other than pile driving (using, *e.g.,* standard barges, tug boats, barge-mounted excavators, or clamshell equipment used to place or remove material), if a marine mammal comes within 10 m, operations shall cease and vessels shall reduce speed to the minimum level required to maintain steerage and safe working conditions.

5. Monitoring and Reporting.

The holder of this Authorization is required to report all monitoring conducted under the IHA within 90 calendar days of the completion of the marine mammal monitoring. This report shall detail the monitoring protocol, summarize the data recorded during monitoring, and estimate the number of marine mammals that may have been harassed. If no comments are received from NMFS within 30 days of submission of the draft final report, the draft final report will constitute the final report. If comments are received, a final report must be submitted within 30 days after receipt of comments:

(a) Marine Mammal Observers (MMOs) must have the following qualifications:

(i) Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the water's surface with ability to estimate target size and distance. Use of spotting scopes and binoculars may be necessary to correctly identify the target;

(ii) Experience and ability to conduct field observations and collect data according to assigned protocols (this may include academic experience);

(iii) Experience or training in the field identification of marine mammals (cetaceans and pinnipeds);

(iv) Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;

(v) Writing skills sufficient to prepare a report of observations that would include such information as the number and type of marine mammals observed; the behavior of marine mammals in the project area during construction; dates and times when observations were conducted; dates and times when in-water construction activities were conducted; dates and times when marine mammals were present at or within the defined disturbance or injury zones; dates and times when in-water construction activities were suspended to avoid injury from construction noise; etc; and

(vi) Ability to communicate orally, by radio or in person, with project personnel to provide real time information on marine mammals observed in the area as necessary.

(b) Visual Marine Mammal Monitoring and Observation:

(i) During impact pile driving, one MMO shall monitor the 1.6-kilometer disturbance zone from the Gustavus Ferry Terminal. The smaller injury zone of 76 meters for whales and 16 meters for pinnipeds will also be monitored by a MMO during impact pile driving. During vibratory driving, one MMO shall monitor the 1.9 km disturbance zone from the Gustavus Ferry Terminal;

(ii) At the beginning of each day, the observer shall determine their vantage positions using a handheld GPS unit. If a MMO changes position throughout the day, each new position will also be determined using a hand-held GPS unit;

(iii) Monitoring shall begin 30 minutes prior to impact pile driving;

(iv) If all marine mammals in the disturbance zone have been documented and no marine mammals are in the injury zone, the coordinator shall instruct the contractor to initiate the soft-start procedure for any impact pile driving;

(v) When a marine mammal is observed, its location shall be determined using a rangefinder to verify distance and a GPS or compass to verify heading;

(vi) If marine mammals listed in 3(b) are observed nearing their respective injury zones, pile-driving activities shall be immediately shut down. Operations shall continue after the animal has been spotted out of the zone or 30 minutes have passed without re-sighting the animal in the zones;

(vii) The MMO shall record all cetaceans and pinnipeds present in the disturbance zones;

(ix) The observer will use their naked eye with the aid of binoculars and a spotting scope to search continuously for marine mammals;

(x) During the in-water operation of heavy machinery (*e.g.,* barge movements), a 10-meter shutdown zone for all marine mammals will be implemented;

(xi) At the end of the pile-driving day, post-construction monitoring will be conducted for 30 minutes beyond the cessation of pile driving; and

(xii) If waters exceed a sea-state which restricts the MMO's ability to make observations within the marine mammal shutdown zone (*e.g.* excessive wind or fog), pile installation will cease. Pile driving will not be initiated until the entire shutdown zone is visible.

(c) During pile driving, one MMO shall be positioned at the best practical vantage point. The monitoring position will be on the ferry terminal, but may vary based on pile driving activities and the locations of the piles and driving equipment. The monitoring location will be identified with the following characteristics:

(i) Unobstructed view of pile being driven;

(ii) Unobstructed view of all water within a 1.6 km (impact driving) or 1.9 km (vibratory driving) radius of each pile;

(iii) Clear view of pile-driving operator or construction foreman in the event of radio failure; and

(iv) Safe distance from pile-driving activities in the construction area.

(d) When possible, ADOT&PF shall augment land-based monitoring with information from boats in Icy Strait/Passage by coordinating with the NPS and whale-watching charters. The MMO shall conduct telephone checks with NPS and whale-watching charters to monitor the locations of humpback whales and Steller sea lions within Icy Strait/Passage.

(e) Data Collection:

Observers are required to use approved data forms. Among other pieces of information, ADOT&PF will record detailed information about any implementation of shutdowns, including the distance of animals to the pile and description of specific actions that ensued and resulting behavior of the animal, if any. In addition, ADOT&PF will attempt to distinguish between the number of individual animals taken and the number of incidents of take. At a minimum, the following information shall be recorded on the sighting forms:

1. Date and time that monitored activity begins or ends;
2. Construction activities occurring during each observation period;

3. Weather parameters (*e.g.,* percent cover, visibility);

4. Water conditions (*e.g.,* sea state, tide state);

5. Species, numbers, and, if possible, sex and age class of marine mammals;

6. Description of any observable marine mammal behavior patterns, including bearing and direction of travel and distance from pile driving activity;

7. Distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point;

8. Locations of all marine mammal observations; and

9. Other human activity in the area.

(f) Reporting Measures:

(i) In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by the IHA, such as an injury (Level A harassment), serious injury or mortality (*e.g.,* ship-strike, gear interaction, and/or entanglement), ADOT&PF would immediately cease the specified activities and immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the Alaska Regional Stranding Coordinators. The report would include the following information:

1. Time, date, and location (latitude/longitude) of the incident;

2. Name and type of vessel involved;

3. Vessel's speed during and leading up to the incident;

4. Description of the incident;

5. Status of all sound source use in the 24 hours preceding the incident;

6. Water depth;

7. Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, and visibility);

8. Description of all marine mammal observations in the 24 hours preceding the incident;

9. Species identification or description of the animal(s) involved;

10. Fate of the animal(s); and

11. Photographs or video footage of the animal(s) (if equipment is available);

(ii) Activities would not resume until NMFS is able to review the circumstances of the prohibited take. NMFS would work with ADOT&PF to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. ADOT&PF would not be able to resume their activities until notified by NMFS via letter, email, or telephone;

(iii) In the event that ADOT&PF discovers an injured or dead marine mammal, and the lead MMO determines that the cause of the injury or death is unknown and the death is relatively recent (*i.e.,* in less than a moderate state of decomposition as described in the next paragraph), ADOT&PF would immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinators. The report would include the same information identified in the paragraph above. Activities would be able to continue while NMFS reviews the circumstances of the incident. NMFS would work with ADOT&PF to determine whether modifications in the activities are appropriate;

(iv) In the event that ADOT&PF discovers an injured or dead marine mammal, and the lead MMO determines that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), ADOT&PF would report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinators, within 24 hours of the discovery. ADOT&PF would provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network.

6. This Authorization may be modified, suspended or withdrawn if the holder fails to abide by the conditions prescribed herein, or if NMFS determines the authorized taking is having more than a negligible impact on the species or stock of affected marine mammals.

Request for Public Comments

NMFS requests comment on our analysis, the draft authorization, and any other aspect of the Notice of Proposed IHA for ADOT&PF's reconstruction of the existing Gustavus Ferry Terminal located in Gustavus, Alaska. Please include with your comments any supporting data or literature citations to help inform our final decision on ADOT&PF's request for an MMPA authorization.

Dated: June 20, 2016.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

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BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD283

Taking of Threatened or Endangered Marine Mammals Incidental to Commercial Fishing Operations; Issuance of Permit

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA), we, NMFS, hereby issue a permit for a period of three years to authorize the incidental, but not intentional, taking of individuals from three marine mammal stocks listed under the Endangered Species Act (ESA) by the Bering Sea and Aleutian Islands (BSAI) pollock trawl and BSAI flatfish trawl fisheries: The Western North Pacific (WNP) stock of humpback whales (*Megaptera novaeangliae*); Central North Pacific (CNP) stock of humpback whales; and Western U.S. stock of Steller sea lions (*Eumetopias jubatus*).

DATES: This permit is effective for a three-year period beginning June 23, 2016.

ADDRESSES: Reference materials for this permit, including the negligible impact determination (NID), are available on the Internet at *http://www.regulations.gov,* identified by Docket Number NOAA–NMFS–2014–0057. Recovery plans for humpback whales and Steller sea lions are available on the Internet at *http://www.nmfs.noaa.gov/pr/recovery/plans.htm#mammals.* Copies of the reference materials are also available upon request from the NMFS Office of Protected Resources, 1315 East-West Highway, 13th Floor, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Jon Kurland, NMFS Alaska Region, 907–586–7638, *Jon.Kurland@noaa.gov;* or Shannon Bettridge, NMFS Office of Protected Resources, 301–427–8402, *Shannon.Bettridge@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Pursuant to section 101(a)(5)(E) of the MMPA, 16 U.S.C. 1361 *et seq.,* NMFS shall for a period of up to three consecutive years, allow the incidental, but not the intentional, taking of marine mammal species listed under the ESA, 16 U.S.C. 1531 *et seq.*, by persons using vessels of the United States and those vessels which have valid fishing permits issued by the Secretary in accordance with section 204(b) of the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1824(b), while engaging in commercial fishing operations, if we make certain determinations. We must determine, after notice and opportunity for public comment, that: (1) Incidental mortality and serious injury will have a negligible impact on the affected species or stocks; (2) a recovery plan has been developed or is being developed for the species or stocks under the ESA; and (3) where required under section 118 of the MMPA, a monitoring program has been established for the fisheries, vessels engaged in the fisheries are registered, and a take reduction plan (TRP) has been developed or is being developed for the species or stocks.

We are issuing a permit under MMPA section 101(a)(5)(E) to vessels registered in the BSAI pollock trawl and BSAI flatfish trawl fisheries to incidentally take individuals from the WNP and CNP stocks of humpback whales and the Western U.S. stock of Steller sea lions. Humpback whales and the western Distinct Population Segment of Steller sea lions are listed as endangered under the ESA. We have determined that incidental taking from these fisheries will have a negligible impact on these stocks, as documented in our NID (see **ADDRESSES**). We have also determined that recovery plans have been completed for humpback whales and Steller sea lions, and in accordance with MMPA section 118, a monitoring program is established for the fisheries and vessels are registered. Finally, we have determined that these fisheries and stocks meet the MMPA trigger for development of a TRP, but they are lower priorities compared to other marine mammal stocks and fisheries based on the levels of incidental mortality and serious injury (M/SI) and population levels and trends. Accordingly, development of TRPs for these three stocks in these two fisheries will be deferred under section 118, since other stocks/fisheries are higher priorities for any available funding for establishing new Take Reduction Teams. The basis for these determinations is further described below.

We recognize that a proposed change to the ESA listing for humpback whales (80 FR 22303 April 21, 2015), if finalized, might affect the need for an MMPA 101(a)(5)(E) permit for these fisheries to incidentally take humpback whales. However, we are including humpback whales in this permit because the species is currently listed as endangered.

Our proposed permit and draft NID addressed two other marine mammals (the Alaska stocks of bearded and ringed seals) and one other fishery (the BSAI Pacific cod longline fishery) (80 FR 78711, December 17, 2015). On July 25, 2014, the U.S. District Court for the District of Alaska issued a memorandum decision in a lawsuit challenging the listing of bearded seals under the ESA (*Alaska Oil and Gas Association* v. *Pritzker*, Case No.4:13–cv–00018–RPB). The decision vacated our listing of the Beringia DPS of bearded seals as a threatened species. On March 11, 2016, the U.S. District Court for the District of Alaska issued a memorandum decision in a lawsuit challenging the listing of ringed seals under the ESA (*Alaska Oil and Gas Association* v. *Pritzker*, Case No.4:14–cv–00029–RRB). The decision vacated our listing of the Arctic subspecies of ringed seals as a threatened species. We are currently appealing these decisions. In the interim, our NID continues to evaluate the impacts of fisheries on the Alaska stocks of bearded and ringed seals under MMPA 101(a)(5)(E), but because the ESA listings for these two species are not currently in effect, we are not including them in this permit and they are not further discussed in this Notice. The BSAI Pacific cod longline fishery has incidental take of the Alaska stock of ringed seals but no other ESA-listed species. We evaluate the impacts of this fishery on the Alaska stock of ringed seals in our NID, but we are not including the fishery in this permit.

A description of the two permitted fisheries can be found in the NID and the **Federal Register** notice for the proposed permit (80 FR 78711, December 17, 2015). These federally-managed fisheries take place inside both state waters (from the coastline out to three nautical miles) and federal waters (three to two hundred nautical miles from shore). The federally-managed fisheries inside Alaska state waters are often referred to as state "parallel" fisheries and are included in this authorization. All other Category II fisheries that interact with ESA-listed marine mammal stocks observed off the coasts of Alaska are state-managed fisheries (as opposed to state parallel fisheries), and are not included in this permit. Participants in Category III fisheries are not required to obtain incidental take permits under MMPA section 101(a)(5)(E) but are required to report injuries or mortality of marine mammals incidental to their operations.

Basis for Determining Negligible Impact

As described above, prior to issuing the permit, we must determine if M/SI incidental to commercial fisheries will have a negligible impact on the affected marine mammal species or stocks. We satisfied this requirement through completion of a NID (see **ADDRESSES**).

Although the MMPA does not define "negligible impact," we have issued regulations providing a qualitative definition of "negligible impact" as defined in 50 CFR 216.103, and through scientific analysis, peer review, and public notice developed a quantitative approach. As it applies here, the definition of "negligible impact" is "an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to adversely affect the species or stock through effects on annual rates of recruitment or survival." The development of the approach is outlined in detail in the NID and was described in previous notices for other permits to take threatened or endangered marine mammals incidental to commercial fishing (*e.g.*, 72 FR 60814, October 26, 2007; 78 FR 54553, September 4, 2013).

In 1999, we proposed criteria to determine whether M/SI incidental to commercial fisheries will have a negligible impact on a listed marine mammal stock for MMPA section 101(a)(5)(E) permits (64 FR 28800, May 27, 1999). In applying the 1999 criteria, Criterion 1 is whether total known, assumed, or extrapolated human-caused M/SI is less than 10 percent of the potential biological removal level (PBR) for the stock. If total known, assumed, or extrapolated human-caused M/SI is less than 10 percent of PBR, the analysis would be concluded, and the impact would be determined to be negligible. If Criterion 1 is not satisfied, we may use one of the other criteria as appropriate. Criterion 2 is satisfied if the total known, assumed, or extrapolated human-caused M/SI is greater than PBR, but fisheries-related M/SI is less than 10 percent of PBR. If Criterion 2 is satisfied, vessels operating in individual fisheries may be permitted if management measures are being taken to address non-fisheries-related mortality and serious injury. Criterion 3 is satisfied if total fisheries-related M/SI is greater than 10 percent of PBR and less than PBR, and the population is stable or increasing. Fisheries may then be permitted subject to individual review and certainty of data. Criterion 4 stipulates that if the population abundance of a stock is declining, the threshold level of 10 percent of PBR will continue to be used. Criterion 5 states that if total fisheries-related M/SI are greater than PBR, permits may not be issued for that species or stock.

Negligible Impact Determinations

The NID provides a complete analysis of the criteria for determining whether commercial fisheries off Alaska are having a negligible impact on the WNP or CNP stocks of humpback whales or the Western U.S. stock of Steller sea lions. A summary of the analysis and subsequent determination follows. The analysis is based on the 2014 marine mammal stock assessment reports (SARs), which estimate mean or minimum annual mortality for 2008–2012 from observed commercial fisheries and entanglement data from the NMFS Marine Mammal Health and Stranding Network. This is the most recent five-year period for which data were available and had been analyzed when the proposed permit and draft NID were being developed. In cases where available observer data are only available outside that time frame, as is the case for state-managed fisheries, the most recent observer data are used.

Humpback Whale, WNP Stock

Total fisheries-related M/SI per year (0.9, 30 percent of PBR) is greater than 10 percent of the stock's PBR but less than PBR (3.0). We expect only minor fluctuations in fisheries-related M/SI. The stock is considered to be increasing: The most recent abundance estimate represents a 6.7 percent annual rate of increase over the previous (1991–1993) estimate, though this rate is biased high to an unknown degree. Therefore, using Criterion 3 we determine that M/SI incidental to commercial fishing will have a negligible impact on the stock.

Humpback Whale, CNP Stock

CNP humpback whales represent a case not considered by the existing criteria, but data support a negligible impact determination. Total annual human-caused M/SI (15.89, 19.19 percent of PBR) is well below the Criterion 2 M/SI threshold (*i.e.*, below PBR) and is expected to remain so for the foreseeable future. Total annual fisheries-related M/SI (3.95, 4.77 percent of PBR) is well below the Criterion 3 M/SI threshold (*i.e*, below PBR) with only minor fluctuations in fisheries-related M/SI expected, and the population is increasing (4.9–10 percent per year, depending on the study and specific area). Therefore, we determine that M/SI incidental to commercial fishing will have a negligible impact on the stock.

Steller Sea Lion, Western U.S. Stock

Total fisheries related M/SI per year (32.7, 11.2 percent of PBR) is greater than 10 percent of the stock's PBR, but less than PBR (292). We expect only minor fluctuations in fisheries-related M/SI. The level of total human-caused M/SI is estimated to be below PBR and is expected to remain below PBR for the foreseeable future. Survey data collected since 2000 indicate that Steller sea lion decline continues in the central and western Aleutian Islands but regional populations east of Samalga Pass have increased or are stable. Overall, the stock is increasing at an annual rate of 1.67 percent (non-pups) and 1.45 percent (pups). Therefore, using Criterion 3 we determine that M/SI incidental to commercial fishing will have a negligible impact on this stock.

Conclusions for the Permit

In conclusion, based on the negligible impact criteria outlined in 1999 (64 FR 28800), the 2014 Alaska SARs, and the best scientific information and data available for the time period analyzed in this permit, we have determined that for a period of up to three years, M/SI incidental to the BSAI pollock trawl and BSAI flatfish trawl fisheries will have a negligible impact on the WNP and CNP stocks of humpback whales and the Western U.S. stock of Steller sea lions.

The impacts on the human environment of continuing and modifying the Bering Sea trawl fisheries, including the taking of threatened and endangered species of marine mammals, were analyzed in the 2004 Alaska Groundfish Fisheries Programmatic Supplemental Environmental Impact Statement (PSEIS). The 2015 Alaska Groundfish Fisheries PSEIS Supplemental Information Report reviewed new information since 2004 and concluded that a new PSEIS was not necessary because (1) management changes to the fisheries since 2004 do not constitute a substantial change in the action, and all changes are consistent with the preferred alternative evaluated in the PSEIS, (2) the current status of the resources can be considered within the range of variability analyzed in the 2004 PSEIS, and (3) although new information exists regarding the impacts of the groundfish fisheries on resources, no information indicates that a new analysis would conclude that there is now a significant impact where the 2004 PSEIS concludes that the impact was insignificant.

Because this permit would not modify any fishery operation and the effects of the fishery operations have been evaluated fully in accordance with NEPA, no additional NEPA analysis is required for this permit. Issuing the permit would have no additional impact to the human environment or effects on threatened or endangered species beyond those analyzed in these documents.

Recovery Plans

Section 4(f) of the ESA requires that we develop recovery plans for ESA-listed species, unless such a plan will not promote the conservation of the species. Recovery Plans for humpback whales and Steller sea lions have been completed (see **ADDRESSES**).

Vessel Registration

MMPA section 118(c) requires that vessels participating in Category I and II fisheries register to obtain an authorization to take marine mammals incidental to fishing activities. Further, section 118(c)(5)(A) provides that registration of vessels in fisheries should, after appropriate consultations, be integrated and coordinated to the maximum extent feasible with existing fisher licenses, registrations, and related programs. MMPA registration for participants in the BSAI trawl fisheries has been integrated with the Federal groundfish limited entry permit process of the Federal Vessel Monitoring System.

Monitoring Program

BSAI trawl fisheries authorized under this permit are monitored by NMFS-certified observers in the North Pacific Groundfish Observer Program. Observer coverage rates range from 50–100 percent. Accordingly, as required by MMPA section 118, a monitoring program is in place for the BSAI pollock trawl and flatfish trawl fisheries.

Take Reduction Plans

MMPA section 118 requires the development and implementation of a TRP in cases where a strategic stock interacts with a Category I or II fishery. The stocks covered under this permit are designated as strategic stocks under the MMPA because they are listed as endangered under the ESA (MMPA section 3(19)(C)). The two fisheries covered by this permit are Category II fisheries. Therefore, the three listed stocks and two fisheries meet the MMPA's triggers for convening a take reduction team (TRT) and developing a TRP.

The obligations to develop and implement a TRP are further subject to the availability of funding. MMPA section 118(f)(3) contains specific priorities for developing TRPs. At this time, we have insufficient funding available to simultaneously develop and implement TRPs for all strategic stocks that interact with Category I or Category II fisheries. As provided in MMPA sections 118(f)(6)(A) and (f)(7), we used the most recent SARs and List of Fisheries (LOF) as the basis to determine our priorities for establishing TRTs and developing TRPs. Through this process, we evaluated the WNP and CNP stocks of humpback whale and the Western U.S. stock of Steller sea lions as lower priorities for establishing TRTs compared to other marine mammal stocks and fisheries, based on M/SI levels incidental to those fisheries and population levels and trends. Accordingly, given these factors and our priorities, developing TRPs for these three stocks in these two fisheries will be deferred under section 118, since other stocks/fisheries are a higher priority for any available funding for establishing new TRTs.

Current Permit

As described above, all of the requirements to issue a permit to Federally-managed BSAI pollock trawl and BSAI flatfish trawl fisheries have been satisfied. Accordingly, we hereby issue a permit to participants in these two fisheries to incidentally take individuals from the WNP and CNP stocks of humpback whales and the Western U.S. stock of Steller sea lions. As noted under MMPA section 101(a)(5)(E)(ii), no permit is required for vessels in Category III fisheries. For incidental taking of marine mammals to be authorized in Category III fisheries, M/SI must be reported to NMFS. If we determine at a later date that incidental M/SI from commercial fishing is having more than a negligible impact on these stocks, we may use our emergency authority under MMPA section 118 to protect the stocks and may modify the permit issued herein.

MMPA section 101(a)(5)(E) requires NMFS to publish in the **Federal Register** a list of fisheries that have been authorized to take threatened or endangered marine mammals. A list of such fisheries was most recently published, as required, on April 23, 2015 (80 FR 22713). With issuance of the current permit, we are not adding any fisheries to this list, but are revising the list of marine mammal species and stocks authorized in the BSAI pollock and flatfish trawl fisheries, and removing the Alaska Bering Sea sablefish pot fishery and the Alaska BSAI Pacific cod longline fishery (Table 1).

TABLE 1—LIST OF FISHERIES AUTHORIZED TO TAKE SPECIFIC THREATENED AND ENDANGERED MARINE MAMMALS INCIDENTAL TO COMMERCIAL FISHING OPERATIONS

Fishery	Category	Marine mammal stock
HI deep-set (tuna target) longline	I	Humpback whale, CNP stock. Sperm whale, Hawaii stock. False killer whale, MHI IFKW stock.
CA thresher shark/swordfish drift gillnet fishery (≤14 in mesh)	I	Fin whale, CA/OR/WA stock. Humpback whale, CA/OR/WA stock. Sperm whale, CA/OR/WA stock.
HI shallow-set (swordfish target) longline/set line	II	Humpback whale, CNP stock.
AK Bering Sea/Aleutian Islands flatfish trawl	II	Humpback whale, WNP stock. Humpback whale, CNP stock. Steller sea lion, Western U.S. stock.
AK Bering Sea/Aleutian Island pollock trawl	II	Humpback whale, WNP stock. Humpback whale, CNP stock. Steller sea lion, Western U.S. stock.
WA/OR/CA sablefish pot fishery	II	Humpback whale, CA/OR/WA stock.

Comments and Responses

NMFS received three comment letters on the proposed permit and draft NID. The Marine Mammal Commission (Commission) supported issuing the permit while two other commenters, Center for Biological Diversity (Center) and an individual, opposed issuing the permit. Only comments pertaining to the draft NID and proposed permit are responded to in this notice.

General Comments

Comment 1: The Center urged NMFS to consult under ESA section 7 on issuing the permit.

Response: This MMPA section 101(a)(5)(E) permit is not a stand-alone action and does not require separate ESA section 7 consultation. NMFS has consulted under ESA section 7 on the BSAI groundfish fishery management plans. The resulting biological opinions analyze the impact of the fishery-related mortalities on ESA-listed marine mammals including the five species analyzed in the NID. This MMPA section 101(a)(5)(E) permit authorizes take of ESA-listed marine mammals under the MMPA while the biological opinions authorize take of ESA-listed marine mammals under the ESA.

Comment 2: The Center recommends that NMFS include state-managed fisheries under this permit. The Center feels that by not including state fisheries in the permit, NMFS is undermining conservation of marine mammals because it implies that state-managed fisheries are not subject to the same take prohibitions as federal fisheries. The Center notes that NMFS has the authority and duty to manage state-managed fisheries under MMPA section 118.

Response: MMPA section 101(a)(5)(E) is one of the links between the MMPA and the ESA. For federally-managed fisheries, NMFS has a federal nexus to consult under ESA section 7 on the activity that may affect ESA-listed species (*e.g.,* commercial fishing by issuing a fishery management plan or an amendment to such a plan). As noted in response to Comment 1, this MMPA permit is linked to federal management of the BSAI groundfish fisheries. The NID considered state fisheries in the analysis, including those with mortality data preceding the time frame for the analysis if those data were the best available, so that impacts of takes from the federally-managed fisheries could be understood in the context of all known fishery-related takes . However, NMFS is not authorizing incidental take of ESA-listed species in state fisheries.

Take of ESA-listed marine mammals in state-managed fisheries is subject to the same prohibitions as federally-managed fisheries. But, without the federal nexus, ESA section 7 does not apply to state fisheries. States are responsible for applying for an incidental take permit under ESA section 10(a)(1)(B) to obtain authorization for takes of ESA-listed species that occur incidental to an otherwise authorized activity (*e.g.*, state-managed fisheries). Unless a state obtains such a permit, any take of ESA-listed species would be unauthorized. NMFS cannot require that a state apply for such a permit; it is the state's responsibility to do so as part of managing state fisheries.

MMPA section 118 provides the framework for addressing marine mammal interactions in commercial fisheries nationwide and includes various metrics and guidance for managing the take reduction program as a whole. First, the program authorizes incidental take of non-ESA-listed marine mammals in commercial fisheries classified as Category I or II (no authorization is required for Category III fisheries). Then, the program directs efforts to reduce M/SI incidental to commercial fisheries and provides for priority-setting when funding is limited. TRPs can and do address marine mammal M/SI in state-managed fisheries. NMFS can authorize incidental take of endangered marine mammals in state fisheries, but is not doing so through this action.

Comment 3: The Center believes that additional mitigation measures to reduce entanglement should be included in the permit given the MMPA's requirement to develop a TRP. Therefore, the Center feels that NMFS cannot authorize these fisheries until such a plan has been developed. Further, the Center requests that NMFS convene a take reduction team to develop a TRP.

Response: As noted in the **Federal Register** notice for the proposed permit (80 FR 78711, December 17, 2015), take reduction requirements are triggered when a strategic stock is killed or seriously injured in Category I or II fisheries. All the stocks addressed by this permit are designated as strategic because they are listed under the ESA (MMPA section 2(19)(C)) and not because fishery-related M/SI exceeds PBR. MMPA section 118 is explicitly designed to reduce fishery-related M/SI below PBR, so while required by the MMPA, TRPs may not be necessary for addressing threats affecting recovery of the species. In recognition of this, a 2008 review of the take reduction program by the Government Accountability Office recommended that Congress consider amending the statutory requirements for establishing a take reduction team to stipulate that not only must a marine mammal stock be strategic and interacting with a Category I or II fishery, but that the fishery with which the marine mammal stock interacts causes at least occasional incidental mortality or serious injury of that particular marine mammal stock (*i.e*, convening teams and developing plans for stocks where fishery-related M/SI is low is contrary to the purpose of this section). Regardless, the obligation to develop and implement TRPs is subject to the availability of funding. MMPA section 118(f)(3) contains specific priorities for developing TRPs. As stated above under Conclusions for the Permit, all stocks authorized to be incidentally taken under this permit are currently lower priorities for developing TRPs compared to other marine mammal stocks and commercial fisheries.

Comment 4: The Center recommends that NMFS include the North Pacific stock of sperm whales in the NID analysis and, if warranted, include this stock under this permit. The commenter notes that the draft NID contains conflicting information, in that at page 19 it reports "M/SI of sperm whales only occurred in the Gulf of Alaska (GOA) sablefish longline fishery (a Category III fishery) in 2007" but Table 5 reflects one observed fishery mortality or serious injury. Further, the draft stock assessment report for sperm whales indicates four serious injuries of sperm whales incidental to the Gulf of Alaska sablefish longline fishery (two each observed in 2012 and 2013). However, NMFS did not provide extrapolated estimates of sperm whale serious injury and mortality stating they were unavailable. Additionally, the Center notes, according to NMFS, because the population size and the PBR for sperm whales are unknown, any fishery interacting with the sperm whale is precluded from qualifying as Category I or II.

Response: The commenter refers to the M/SI of a sperm whale from 2007, which precedes the time frame analyzed for this permit (2008–2012). Table 5 refers to M/SI of Steller sea lions and not to sperm whales. We reviewed the 2014 and 2015 SARs for North Pacific sperm whales per the comment, and recognize that NMFS mistakenly omitted the 2012 serious injuries incidental to the GOA sablefish longline fishery in the 2014 SAR, which includes 2008–2012 data. The 2015 draft SAR includes the 2012 observed serious injuries and notes that the extrapolated estimate is not available. NMFS is currently analyzing these data and intends to include the resulting bycatch estimates in the 2016 draft SAR. When this information has been incorporated into the 2016 draft SAR, NMFS will then evaluate it for the next annual LOF, likely the 2017 LOF. If the GOA sablefish longline fishery is elevated to Category I or II in a future LOF, NMFS will evaluate the need for incidental take permit under MMPA section 101(a)(5)(E). This process is iterative and we will evaluate the best available data at the time we undertake our analysis to issue these permits.

The commenter notes that stocks without minimum abundance estimates are precluded from being considered in the LOF tier analysis, thereby precluding any fisheries that kill or seriously injure those stocks from being classified as Category I or II fisheries. This is incorrect. NMFS may classify fisheries by analogy to other similar fisheries based on various factors (50 CFR 229.2). The commenter references other Category I and II fisheries that take sperm whales, including two pelagic longline fisheries and a drift gillnet fishery. These gear types are not analogous to the GOA sablefish longline fishery, which is a demersal longline fishery, in that the gear used and the fishing practices are substantially different from one another. Both fishing gear and fishing practices are typically related to the risk of entanglement. That said, NMFS will conduct a full evaluation of this stock and this fishery pursuant to the LOF.

Humpback Whales

Comment 5: The notice and draft NID state that the population of Western North Pacific humpback whales is estimated to be increasing at an annual rate of 6.7 percent, but the Commission believes the rate of increase is likely an overestimate because the 2004–06 study included an area not surveyed in the 1991–1993 study. Therefore, the Commission suggested NMFS consider estimating the rate of increase based only on data from sites surveyed in both 1991–93 and 2004–06 to evaluate whether that analysis indicates a clearly stable or increasing trend, which would support the draft NID.

Response: This analysis is part of a larger ongoing analysis of the SPLASH (Structure of Populations, Levels of Abundance and Status of Humpback Whales in the North Pacific) effort. When the results are available, we will evaluate whether any of the findings in the NID would change and take appropriate action at that time.

Comment 6: The Commission is concerned that the WNP population of humpback whales may consist of two distinct population segments (DPS) under the recent proposed ESA listing rule (80 FR 22304, April 21, 2015) whose feeding range overlaps that of the CNP population of humpbacks. If that is the case, population trends for the two putative western North Pacific DPSs may not be the same and the BSAI groundfish fisheries could have a negligible impact on one stock, but more than a negligible impact on the other. Thus, the Commission encourages NMFS to collect and analyze additional information on the discreteness of the two putative Western North Pacific DPSs identified by the humpback whale Biological Review Team.

Response: For the NID, we analyzed the stocks as currently defined in the SARs. The ESA listing rule has not been finalized. NMFS uses the best available data at the time of the analysis and generally does not collect new data for the purposes of issuing an MMPA section 101(a)(5)(E) permit.

Comment 7: The Commission recommended that NMFS consult with researchers to gather data and develop new abundance estimates for the Western North Pacific stock of humpback whales before issuing a subsequent permit.

Response: NMFS agrees that additional, new data would be useful and will continue to collaborate with those researchers collecting data on the Western North Pacific stock of humpback whales.

Comment 8: The Commission encouraged NMFS to instruct fishery observers to collect tissue samples or photographs of all humpback whales take incidental to fisheries to appropriately identify the stock.

Response: Fishery observers are already instructed to take photographs and collect tissue samples when possible. In some cases, as examples, the interaction occurs too quickly or too far from the vessel and photographs/tissue samples may not be possible. Regardless, it has been our practice to assign a take to both stocks so that we can evaluate the impact of that mortality on each stock separately.

Comment 9: The Center recommends that for humpback whales NMFS include the most recent observer data from 2013 and the resulting M/SI estimate in the NID. Specifically, the Center suggests that NMFS consider extrapolating observer data from all fisheries, including the Southeast Alaska drift gillnet fishery, to calculate mean or minimum annual mortality estimates as well as including stranding data from the marine mammal unusual mortality event that began in May 2015 in the western GOA. The Center feels that given the 2013 observer data and the 2015 stranding data, a significant number of animals may have been removed from the population and the extent of M/SI incidental to commercial fishing is unacceptably high.

Response: These permits are iterative and cyclical; they are effective for 3 years per the MMPA. This means that NMFS is regularly considering the most recent information available in the NID analysis to support issuing these permits every three years. This particular permit is based on the 2014 final SAR, which includes 2008–2012 data. We will consider 2013 and 2015 data in future iterations of this permit. New data become available all the time; if we are constantly updating and revising the analysis it will hinder our ability to take action and issue permit decisions.

Steller Sea Lions

Comment 10: The Commission recommends that NMFS consider amending its criteria for making NIDs under section 101(a)(5)(E) of the MMPA to ensure that for declining marine mammal populations listed as endangered or threatened under the ESA, the estimated M/SI by commercial fisheries does not result in a statistically significantly increase in the rate of decline across a large portion of their geographic range. With regard to the western U.S. stock of Steller sea lions, before making a NID for the fisheries subject to this action, NMFS should evaluate M/SI in the three BSAI groundfish fisheries relative to the species' abundance in areas west of Samalga Pass where sea lion numbers have been declining.

Response: NMFS appreciates the suggestion for amending the NID criteria and we will consider as we revise those criteria. As we note in the response to *Comment 2,* NMFS uses the best available information at the time of the NID analysis, including the currently identified range and trends as provided in the most recent SAR. Therefore, we are not conducting a new analysis at this time. With respect to observing the fishery, it is currently monitored both east and west of Samalga Pass and those data are incorporated into the stock assessment.

Bearded and Ringed Seals

Comment 11: The Commission notes that if, indeed, only 2 bearded seals are killed or seriously injured each year by commercial fisheries out of nearly 6,800 removals from the population, it is difficult to see how fisheries-related mortality can be considered significant even if overall PBR is exceeded. Given the removals of bearded and ringed seals by subsistence hunting, the Commission recommends that NMFS consider amending its criteria for making NIDs under section 101(a)(5)(E) of the MMPA to cover situations where (1) the level of mortality and serious injury exceeds or likely exceeds PBR primarily due to subsistence hunting, (2) subsistence hunting is determined to be sustainable, and (3) fishery-related take is a very small fraction of overall removals (*e.g.,* <1.0 percent).

Response: NMFS appreciates the suggestion for amending the NID criteria and we will consider it as we revise those criteria.

Comment 12: The Commission raised concerns about the availability of reliable and up-to-date estimates of population size and subsistence harvest and feels that NMFS is not providing adequate funding to generate these estimates. Given the importance of subsistence hunting to Alaska Native communities and the possible effects of climate change on the abundance and health of ice seals, the Commission believes that NMFS must (1) in cooperation with its co-management partners, identify the essential components of ongoing programs to monitor the abundance and trends of ice seal populations and the number of seals taken by Native hunters, and (2) ensure that funding is adequate to implement those programs. The Commission therefore recommends that NMFS consult with the Alaska Native Ice Seal Committee to identify the steps necessary to carry out adequate ice seal population surveys and harvest monitoring programs, and seek the funding necessary to implement them. The Commission recognizes NMFS's constraints on funding for marine mammal research and management, but believes it is imperative that these needs receive higher priority.

Response: NMFS recently conducted a protected species science program review of the Alaska Fisheries Science Center (AFSC). The review generated several recommendations related to ice seals. Recommendation 1.5 directs NMFS to develop an explicit strategy for assessing all stocks, considering costs, likely available funds, and scientific and management priorities. In its response, in 2015–2016, the NMFS AFSC committed to developing a proposed strategy for assessing all marine mammal stocks and including that strategy and a system for prioritizing those assessments in the 5-year plan for the AFSC. Regardless, abundance surveys for ice seals are ongoing, with another scheduled for 2016, which are intended to result in an abundance estimate. Additionally, Recommendation 1.6 directs NMFS to pursue support for bycatch and harvest monitoring in particularly risky fisheries or regions. The AFSC response notes that monitoring harvest levels is currently unfunded, and while resources are limited the AFSC will work with the NMFS Alaska Regional Office to develop a joint list of priorities for understanding harvest levels so both entities can solicit additional resources and coordinate to achieve this objective.

Dated: June 20, 2016.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–14866 Filed 6–22–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Legal Processes

ACTION: Notice and request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on this continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before August 22, 2016.

ADDRESSES: You may submit comments by any of the following methods:

- *Email: InformationCollection@uspto.gov.* Include "0651–0046 inquiry" in the subject line of the message.
- *Federal Rulemaking Portal: http://www.regulations.gov.*
- *Mail:* Marcie Lovett, Records Management Division Director, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Kyu Lee, Office of General Law, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–6421; or by email at *Kyu.Lee@uspto.gov* with "0651–0046 inquiry" in the subject line. Additional information about this collection is also available at *http://www.reginfo.gov* under "Information Collection Review."

SUPPLEMENTARY INFORMATION:

I. Abstract

The purpose of this collection is to cover information requirements related to civil actions and claims involving current and former employees of the United States Patent and Trademark Office (USPTO). The rules for these legal processes may be found under 37 CFR part 104, which outlines procedures for service of process, demands for employee testimony and production of documents in legal proceedings, reports of unauthorized testimony, employee indemnification, and filing claims against the USPTO under the Federal Tort Claims Act (28 U.S.C. 2672) and the corresponding Department of Justice regulations (28 CFR part 14). The public may also petition the USPTO Office of General Counsel under 37 CFR 104.3 to waive or suspend these rules in extraordinary cases.

The procedures under 37 CFR part 104 ensure that service of process intended for current and former employees of the USPTO is handled properly. The USPTO will only accept service of process for an employee acting in an official capacity. This collection is necessary so that respondents or their representatives can serve a summons or complaint on the USPTO, demand employee testimony and documents related to a legal proceeding, or file a claim under the Federal Tort Claims Act. Respondents may also petition the USPTO to waive or suspend these rules for legal processes. This collection is also necessary so that current and former USPTO employees may properly forward service and demands to the Office of General Counsel, report unauthorized testimony, and request indemnification. The USPTO covers current employees as respondents under this information collection even though their responses do not require approval under the Paperwork Reduction Act. In those instances where both current and former employees may respond to the USPTO, the agency estimates that the number of respondents will be small.

There are no forms provided by the USPTO for this collection. For filing claims under the Federal Tort Claims Act, the public may use Standard Form 95 "Claim for Damage, Injury, or Death," which is provided by the Department of Justice and approved by the Office of Management and Budget (OMB) under OMB Control Number 1105–0008.

II. Method of Collection

By mail or hand delivery to the USPTO.

III. Data

OMB Number: 0651–0046.

Form Number(s): None.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or households; businesses or other for-profits; not-for-profit institutions; and the Federal Government.

Estimated Number of Respondents: 299 responses per year. The USPTO estimates that approximately 10% of these responses will be from small entities.

Estimated Time per Response: The USPTO estimates that it will take the public from 5 minutes (0.08 hours) to 6 hours to prepare a single item in this collection, including gathering the necessary information, preparing the appropriate documents, and submitting the information required for this collection.

Estimated Total Annual Hour Burden: 87.08 hours.

Estimated Total Annual Cost Burden (Hourly): $35,539.05. The USPTO expects that the information in this collection will be prepared by attorneys and former employees at an hourly rate of $410, except for the requests for employee indemnification, which generally come from professional and supervisory staff at an hourly rate of $79.78. Since the majority of the former employees affected by this collection are attorneys, the estimated attorney hourly rate will be used for former employees as well. Using these hourly rates, the USPTO estimates that the total respondent cost burden for this collection will be approximately $35,539.05 per year.

TABLE 1—RESPONDENT HOURLY COST BURDEN

IC No./Item	Estimated response time (hours) (a)	Estimated annual responses (b)	Estimated annual burden hours (a) × (b) = (c)	Rate ($/hr) (d)	Total cost ($/yr) (c) × (d) = (e)
1. Petition to Waive Rules	0.50	5	2.50	$410.00	$1,025.00

TABLE 1—RESPONDENT HOURLY COST BURDEN—Continued

IC No./Item	Estimated response time (hours) (a)	Estimated annual responses (b)	Estimated annual burden hours (a) × (b) = (c)	Rate ($/hr) (d)	Total cost ($/yr) (c) × (d) = (e)
2. Service of Process	0.08	243	20.25	410.00	8,302.50
3. Forwarding Service	0.17	7	1.17	410.00	478.33
4. Employee Testimony and Production of Documents in Legal Proceedings	1.00	23	23.00	410.00	9,430.00
5. Forwarding Demands	0.17	10	1.67	410.00	683.33
6. Report of Unauthorized Testimony	0.50	1	0.50	410.00	205.00
7. Report of Possible Indemnification Cases	0.50	3	1.50	410.00	615.00
8. Employee Indemnification	0.50	1	0.50	79.78	39.89
9. Tort Claims	6.00	6	36.00	410.00	14,760.00
Totals	....	299	87.08	....	35,539.05

Estimated Total Annual Non-hour Respondent Cost Burden: $3,436. There are no capital start-up, maintenance, or recordkeeping costs associated with this information collection. However, this collection does have annual (non-hour) costs in the form of filing fees and postage costs.

Filing Fees

This collection has filing fees associated with the petition to waive or suspend the legal process rules under 37 CFR 104.3. The USPTO estimates that 5 petitions will be filed per year with a fee of $130, for a total fee cost of $650. There are no other fees associated with this information collection.

Postage Costs

Customers may incur postage costs when submitting the information in this collection to the USPTO by mail. The USPTO estimates that the average first-class postage for a mailed submission, other than a Service of Process, will be $0.94 and that up to 56 of these submissions will be mailed to the USPTO per year, for a postage cost of $52.64. The USPTO estimates that the average postage for a Service of Process will be $11.35 and that up to 243 of these submissions will be mailed to the USPTO per year, for a postage cost of $2,758.05. The estimated postage cost for this collection is $2,810.69 per year.

Therefore, the total annual (non-hour) respondent cost burden for this collection, in the form of filing fees ($650.00) and postage costs ($2,810.69), is estimated to be approximately $3,460.69 per year.

IV. Request for Comments

Comments are invited on:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they will also become a matter of public record.

Dated: June 16, 2016.

Marcie Lovett,

Records Management Division Director, OCIO, United States Patent and Trademark Office.

[FR Doc. 2016–14856 Filed 6–22–16; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Promoting Student Resilience

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

Overview Information: Promoting Student Resilience.

Notice inviting applications for new awards for fiscal year (FY) 2016.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.184C.

DATES:

Applications Available: June 23, 2016.

Deadline for Transmittal of Applications: July 25, 2016.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The Promoting Student Resilience program provides grants to local educational agencies (LEAs) (or consortia of LEAs) to build and increase their capacity to address the comprehensive behavioral and mental health needs of students in communities that have experienced Significant civil unrest[1] in the past 24 months.

Background: Recent events have demonstrated that incidents involving civil unrest can disrupt schools and adversely impact the learning environment. These experiences can traumatize students, and this trauma can have lasting adverse effects on the mental, social, and emotional well-being of children and youth. The communities that are directly impacted by Significant civil unrest often have a long history of poverty, neglect, and inequality, and students in these communities often face barriers to accessing social and health services. It is widely recognized that there may also be a history of tension in the relationships between members of the community and agents of the public sector that deters efforts to seek such services.

According to the Substance Abuse and Mental Health Services Administration (SAMHSA), trauma results from an event or a series of events, or a set of circumstances that is perceived by an individual as physically or emotionally harmful or life threatening and that has lasting adverse effects on the individual's mental, social, or emotional well-being.[2]

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[1] Defined terms are used throughout the notice and are indicated by capitalization.

[2] Substance Abuse and Mental Health Services Administration. SAMHSA's Concept of Trauma and Guidance for a Trauma-Informed Approach. HHS Publication No. (SMA) 14–4884. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.

Priorities: This notice contains one absolute priority and two competitive preference priorities. We are establishing these priorities for the FY 2016 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA), 20 U.S.C. 1232(d)(1).

Absolute Priority: This priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet this priority.

This priority is:

Grants to Local Educational Agencies (LEAs) to Provide School-Based Supports to Address the Behavioral and Mental Health Needs of Students in Communities That Have Experienced Significant Civil Unrest.

Under this priority, we provide grants to LEAs (or consortia of LEAs) in communities that have experienced Significant civil unrest to expand the capacity of those LEAs to more effectively address the behavioral and mental health needs of affected students in those communities. An increased capacity of enhanced social and emotional supports, combined with other school-based strategies, will offer schools an opportunity to create, strengthen, and maintain safe and supportive learning environments. These projects must:

(a) Expand the capacity of the LEA(s) to more effectively address the behavioral and mental health needs of students, and

(b) Provide increased access for students to school-based counseling services, or referrals to community-based counseling services, for assistance in coping with trauma.

Competitive Preference Priorities: These priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(1) we award up to an additional 10 points to an application that meets Competitive Preference Priority 1, depending on how well the application meets this priority. We also award 5 points on an all or nothing basis to an application that meets Competitive Preference Priority 2. Therefore, the maximum number of competitive preference priority points that an application can receive under this competition is 15 points.

These priorities are:

Competitive Preference Priority 1—Coordination with Community-Based Organizations.

Under this priority, we provide up to an additional 10 points to an applicant based on the application's description of a credible, high-quality plan to coordinate activities that would be funded under the proposed project with related activities that would be conducted under other programs for which the applicant currently has, or is seeking, funding, including, but not limited to, the Substance Abuse and Mental Health Service Administration's Resiliency in Communities After Stress and Trauma grant program (CFDA 93.243). The coordination plan must include: (1) A description of how the applicant will coordinate with Community-based organizations with experience carrying out similar or related activities to promote student resilience; and (2) evidence of collaboration and coordination through letters of support or a memorandum of understanding from the entities with which the collaboration and coordination will occur. Applicants that receive additional competitive preference points under this priority and who are ultimately awarded a Promoting Student Resilience grant must finalize and implement the high-quality plan described in response to this priority within six months of the grant award.

Competitive Preference Priority 2—Emergency Declaration Status.

Under this priority, we provide an additional 5 points to an applicant from a community in which Significant civil unrest resulted in an emergency declaration from the governor. Applicants must provide a copy of the Governor's declaration in the application.

Application Requirements: We are establishing these requirements for the FY 2016 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA), 20 U.S.C. 1232(d)(1).

To be eligible for a grant under this competition, an application must include, in addition to the items in the plan listed under Program Requirements, the following:

(a) A description of Significant civil unrest experienced by the LEA(s) and its impact on the learning environment in specific schools;

(b) A Logic model for how the applicant will use grant funds effectively;

(c) A needs assessment of students who, as a result of exposure to Significant civil unrest, would benefit from enhanced or increased behavioral and mental health services. This needs assessment must include input from parents;

(d) A capacity assessment of the LEA's, or LEAs', service delivery system's ability to provide mental and behavioral health services; and

(e) A plan to successfully meet the program requirements for this competition, based on data from the needs assessment and the capacity assessment.

Program Requirements: We are establishing these requirements for the FY 2016 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA), 20 U.S.C. 1232(d)(1).

Each grantee must implement a plan described in its approved application to:

(a) Develop, enhance and increase its capacity to provide school-based mental health and behavioral services including, but not limited to:

(1) Providing professional development opportunities for LEA and school mental health staff on how to screen for and respond to civil unrest-related trauma and implement strategies appropriate for school-based mitigation of trauma;

(2) Improving the range, availability, and quality of school-based supports by hiring qualified mental health professionals with experience or training in the behavioral and mental health needs of youth who have experienced trauma related to recent events in their communities; and

(3) Providing training to select school staff, community partners, youth, and parents on the challenges due to exposure to the trauma related to recent events in their communities, and on the importance of screening students and providing interventions to help students cope with traumatic events; and

(b) Providing enhanced or increased behavioral and mental health services and supports while also increasing the grantee's capacity to provide those services and supports.

Definitions: We are establishing the definition of "significant civil unrest" and "community-based organization" in this notice for the FY 2016 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of GEPA, 20 U.S.C. 1232(d)(1). The definition of "local educational agency" is from section 9101(26) of the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the No Child Left Behind Act of 2001 (NCLB) (20 U.S.C. 7801). The definitions of "baseline," "evidence of promise," "logic model," "quasi-experimental design study," "randomized controlled trial," and "relevant outcome" are from 34 CFR 77.1.

Baseline means the starting point from which performance is measured and targets are set.

Community-based organization means a private or public nonprofit organization of demonstrated effectiveness that:

(1) Is representative of a community or significant segments of a community;

(2) provides educational or related services to individuals in the community; and

(3) has experience carrying out activities promoting student resilience.

Evidence of promise means there is empirical evidence to support the theoretical linkage(s) between at least one critical component and at least one Relevant outcome presented in the logic model for the proposed process, product, strategy, or practice. Specifically, evidence of promise means the conditions in both paragraphs (i) and (ii) of this definition are met:

(i) There is at least one study that is a—

(A) Correlational study with statistical controls for selection bias;

(B) Quasi-experimental design study that meets the What Works Clearinghouse Evidence Standards with reservations; or

(C) Randomized controlled trial that meets the What Works Clearinghouse Evidence Standards with or without reservations.

(ii) The study referenced in paragraph (i) of this definition found a statistically significant or substantively important (defined as a difference of 0.25 standard deviations or larger) favorable association between at least one critical component and one Relevant outcome presented in the logic model for the proposed process, product, strategy, or practice.

Local educational agency (LEA) means:

(1) A public board of education or other public authority legally constituted within a State for either administrative control or direction of, or to perform a service function for, public elementary schools or secondary schools in a city, county, township, school district, or other political subdivision of a State, or of or for a combination of school districts or counties that is recognized in a State as an administrative agency for its public elementary schools or secondary schools.

(2) The term includes any other public institution or agency having administrative control and direction of a public elementary school or secondary school.

(3) The term includes an elementary school or secondary school funded by the Bureau of Indian Affairs but only to the extent that including the school makes the school eligible for programs for which specific eligibility is not provided to the school in another provision of law and the school does not have a student population that is smaller than the student population of the local educational agency receiving assistance under the ESEA with the smallest student population, except that the school shall not be subject to the jurisdiction of any State educational agency other than the Bureau of Indian Affairs.

(4) The term includes educational service agencies and consortia of those agencies.

(5) The term includes the State educational agency in a State in which the State educational agency is the sole educational agency for all public schools.

Logic model (also referred to as theory of action) means a well-specified conceptual framework that identifies key components of the proposed process, product, strategy, or practice (*i.e.*, the active "ingredients" that are hypothesized to be critical to achieving the Relevant outcome(s)) and describes the relationships among the key components and outcomes, theoretically and operationally.

Quasi-experimental design study means a study using a design that attempts to approximate an experimental design by identifying a comparison group that is similar to the treatment group in important respects. These studies, depending on design and implementation, can meet What Works Clearinghouse Evidence Standards with reservations (but not What Works Clearinghouse Evidence Standards without reservations).

Randomized controlled trial means a study that employs random assignment of, for example, students, teachers, classrooms, schools, or districts to receive the intervention being evaluated (the treatment group) or not to receive the intervention (the control group). The estimated effectiveness of the intervention is the difference between the average outcomes for the treatment group and for the control group. These studies, depending on design and implementation, can meet What Works Clearinghouse Evidence Standards without reservations.

Relevant outcome means the student outcome(s) (or the ultimate outcome if not related to students) the proposed process, product, strategy, or practice is designed to improve; consistent with the specific goals of a program.

Significant civil unrest means demonstrations of mass protest that included law enforcement involvement that occurred within 24 months immediately prior to June 23, 2016.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities, definitions, and requirements. Section 437(d)(1) of GEPA, however, allows the Secretary to exempt from rulemaking requirements, regulations governing the first grant competition under a new or substantially revised program authority. This is the first grant competition for this program under section 4121 of the Elementary and Secondary Education Act as amended by the No Child Left Behind Act of 2001 and therefore qualifies for this exemption. In order to ensure timely grant awards, the Secretary has decided to forego public comment on the priorities, requirements, and definitions under section 437(d)(1) of GEPA. These priorities, requirements, and definitions will apply to the FY 2016 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition.

Program Authority: 20 U.S.C. 7131, and Title III of Division H of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113).

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 79, 81, 82, 84, 97, 98, and 99. (b) The Office of Management and Budget (OMB) Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The regulations in 34 CFR part 299.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $4,750,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2017 from the list of unfunded applications from this competition.

Estimated Range of Awards: $1,187,500–$2,375,000.

Estimated Average Size of Awards: $1,500,000.

Maximum Award: We will not fund any portion of a budget request exceeding $2,375,000 for a budget period of 24 months. The Assistant Secretary for Elementary and Secondary Education may change the maximum amount through a notice published in the **Federal Register**.

Estimated Number of Awards: 2–4.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 24 months.

III. Eligibility Information

1. *Eligible Applicants:* LEAs, or consortia of LEAs, from a community that has experienced Significant civil unrest.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Other:* Participation by Private School Children and Teachers. Section 9501 of the ESEA requires that SEAs, LEAs, or other entities receiving funds under the Safe and Drug-Free Schools and Communities Act provide for the equitable participation of private school children, their teachers, and other educational personnel in private schools located in geographic areas served by the grant recipient.

In order to ensure that grant program activities address the needs of private school children, the applicant must engage in timely and meaningful consultation with appropriate private school officials during the design and development of the proposed program. This consultation must take place before the applicant makes any decision that affects the opportunities of eligible private school children, teachers, and other educational personnel to participate in grant program activities. The eligible entity should engage in a process of timely and meaningful consultation with private school officials and provide them with information related to the projected and final funding amounts for programs and services, including on the process the entity will use in preparing its competitive grant application. Administrative direction and control over grant funds must remain with the grantee.

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet or from the Education Publications Center (ED Pubs). To obtain a copy via the Internet, use the following address: *www.ed.gov/fund/grant/apply/grantapps/index.html.* To obtain a copy from ED Pubs, write, fax, or call: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov.*

If you request an application package from ED Pubs, be sure to identify this program or competition as follows: CFDA number 84.184C.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the person or team listed under *Accessible Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this program.

Page Limit: The application narrative is where you, the applicant, provide the project narrative to address the selection criteria that reviewers use to evaluate your application. The required budget and budget narrative will be provided in a separate section. You must limit the application narrative to the equivalent of no more than 30 pages, using the following standards:

- A "page" is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the page limit does apply to all of the application narrative section.

Our reviewers will not read any pages of your application that exceed the page limit.

3. *Submission Dates and Times:*

Applications Available: June 23, 2016.

Deadline for Transmittal of Applications: July 25, 2016.

Applications for grants under this program must be submitted electronically using the *Grants.gov* Apply site (*Grants.gov*). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to *Other Submission Requirements* in section IV of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. However, under 34 CFR 79.8(a), we waive intergovernmental review in order to make awards by the end of FY 2016.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM) (formerly the Central Contractor Registry), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following Web site: *http://fedgov.dnb.com/*

webform. A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

Note: Once your SAM registration is active, it may be 24 to 48 hours before you can access the information in, and submit an application through, *Grants.gov*.

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov*. To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a *SAM.gov* Tip Sheet, which you can find at: *http://www2.ed.gov/fund/grant/apply/sam-faqs.html*.

In addition, if you are submitting your application via *Grants.gov*, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with *Grants.gov* as an AOR. Details on these steps are outlined at the following *Grants.gov* Web page: *www.grants.gov/web/grants/register.html*.

7. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications*.

Applications for grants under the Promoting Student Resilience Program, CFDA number 84.184C, must be submitted electronically using the Governmentwide *Grants.gov* Apply site at *www.Grants.gov*. Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement*.

You may access the electronic grant application for the Promoting Student Resilience Program at *www.Grants.gov*. You must search for the downloadable application package for this program by the CFDA number. Do not include the CFDA number's alpha suffix in your search (*e.g.*, search for 84.184, not 84.184C).

Please note the following:

- When you enter the *Grants.gov* site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by *Grants.gov* are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the *Grants.gov* system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the *Grants.gov* system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from *Grants.gov*, we will notify you if we are rejecting your application because it was date and time stamped by the *Grants.gov* system after 4:30:00 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through *Grants.gov*.
- You should review and follow the Education Submission Procedures for submitting an application through *Grants.gov* that are included in the application package for this program to ensure that you submit your application in a timely manner to the *Grants.gov* system. You can also find the Education Submission Procedures pertaining to *Grants.gov* under News and Events on the Department's G5 system home page at *www.G5.gov*. In addition, for specific guidance and procedures for submitting an application through *Grants.gov*, please refer to the *Grants.gov* Web site at: *www.grants.gov/web/grants/applicants/apply-for-grants.html*.
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- You must upload any narrative sections and all other attachments to your application as files in a read-only, non-modifiable Portable Document Format (PDF). Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF (*e.g.*, Word, Excel, WordPerfect, etc.) or submit a password-protected file, we will not review that material. Please note that this could result in your application not being considered for funding because the material in question—for example, the project narrative—is critical to a meaningful review of your proposal. For that reason it is important to allow yourself adequate time to upload all material as PDF files. The Department will not convert material from other formats to PDF.
- Your electronic application must comply with any page-limit requirements described in this notice.
- After you electronically submit your application, you will receive from *Grants.gov* an automatic notification of receipt that contains a *Grants.gov* tracking number. This notification indicates receipt by *Grants.gov* only, not receipt by the Department. *Grants.gov* will also notify you automatically by email if your application met all the *Grants.gov* validation requirements or if there were any errors (such as

submission of your application by someone other than a registered Authorized Organization Representative, or inclusion of an attachment with a file name that contains special characters). You will be given an opportunity to correct any errors and resubmit, but you must still meet the deadline for submission of applications.

Once your application is successfully validated by *Grants.gov*, the Department will retrieve your application from *Grants.gov* and send you an email with a unique PR/Award number for your application.

These emails do not mean that your application is without any disqualifying errors. While your application may have been successfully validated by *Grants.gov*, it must also meet the Department's application requirements as specified in this notice and in the application instructions. Disqualifying errors could include, for instance, failure to upload attachments in a read-only, non-modifiable PDF; failure to submit a required part of the application; or failure to meet applicant eligibility requirements. It is your responsibility to ensure that your submitted application has met all of the Department's requirements.

- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through *Grants.gov*, please contact the *Grants.gov* Support Desk, toll free, at 1–800–518–4726. You must obtain a *Grants.gov* Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the *Grants.gov* system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with *Grants.gov*, along with the *Grants.gov* Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the *Grants.gov* system and that the problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. We will contact you after we determine whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the *Grants.gov* system. We will not grant you an extension if you failed to fully register to submit your application to *Grants.gov* before the application deadline date and time or if the technical problem you experienced is unrelated to the *Grants.gov* system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the *Grants.gov* system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the *Grants.gov* system; and
- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Deirdra Hilliard, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E–249, Washington, DC 20202–6450. FAX: (202) 453–6742.

Your paper application must be submitted in accordance with the mail or hand-delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address:
U.S. Department of Education,
Application Control Center, Attention:
(CFDA Number 84.184C), LBJ Basement
Level 1, 400 Maryland Avenue SW.,
Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

We will not consider applications postmarked after the application deadline date.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.184C), 550 12th Street SW., Room 7039, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program are from 34 CFR

75.210 of EDGAR. All of the selection criteria are listed in this section and in the application package. The maximum score for all of the selection criteria is 100 points. The maximum score for each criterion is included in parentheses following the title of the specific selection criterion. Each criterion also includes one or more factors that reviewers will consider in determining the extent to which an applicant meets the criterion. Points awarded under these selection criteria are in addition to any points an applicant earns under the competitive preference priorities in this notice. The maximum score that an application may receive under the competitive preference priorities and the selection criteria is 115 points.

1. *Need for Project.* (20 points)

The Secretary considers the need for the proposed project. In determining the need for the proposed project, the Secretary considers the following factors:

(a) The magnitude of the need for the services to be provided or the activities to be carried out by the proposed project. (10 points)

(b) The extent to which specific gaps or weaknesses in services, infrastructure or opportunities have been identified and will be addressed by the proposed project including the nature and magnitude of those gaps or weaknesses. (10 points)

2. *Quality of the Project Design.* (45 points)

The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(a) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs. (15 points)

(b) The extent to which the proposed project will integrate with or build on similar or related efforts in order to improve Relevant outcome(s) (as defined in 34 CFR 77.1(c)), using existing funding streams from other programs or policies supported by community, State, and Federal resources. (10 points)

(c) The extent to which the proposed project is supported by Evidence of promise (as defined in 34 CFR 77.1(c)). (10 points)

(d) The extent to which the proposed project will establish linkages with other appropriate agencies and organizations providing services to the target population. (5 points)

(e) The extent to which the proposed project encourages parental involvement. (5 points)

3. *Quality of Project Personnel.* (10 points)

The Secretary considers the quality of the personnel who will carry out the proposed project.

(a) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. (5 points)

In addition, the Secretary considers the following factor:

(b) The qualifications, including relevant training and experience, of key project personnel. (5 points)

4. *Quality of the Management Plan.* (15 points)

The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan of the proposed project, the Secretary considers the following factor:

(a) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks. (15 points)

5. *Quality of the Project Evaluation.* (10 points)

The Secretary considers the quality of the project evaluation to be conducted of the proposed project. In determining the quality of the evaluation of the proposed project, the Secretary considers the following factor:

(a) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project. (10 points)

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this program the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR

75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

4. *Performance Measures:* (a) The Department has established the following performance measures for assessing the effectiveness of the Promoting Student Resilience grant program:

1. The number of students served by the grant(s) receiving school-based and community mental health services to address student needs resulting from exposure to trauma; and
2. The number of Community-based organizations that are coordinating and sharing resources with each other as a result of the grant(s).

(b) Baseline data. Applicants must provide Baseline data for each of the performance measures listed in (a) and explain why each proposed Baseline is valid; or, if the applicant has determined that there are no established Baseline data for a particular performance measure, explain why there is no established Baseline and explain how and when, during the project period, the applicant will establish a valid Baseline for the performance measure.

Note: If the applicant does not have experience with collection and reporting of performance data through other projects or research, the applicant should provide other evidence of capacity to successfully carry out data collection and reporting for its proposed project. These measures constitute the Department's indicators of success for this program. Consequently, we advise an applicant for a grant under this program to give careful consideration to these measure in conceptualizing the approach and evaluation for its proposed project. Each grantee will be required to provide, in its annual performance and final reports, data about its progress in meeting these measures.

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Deirdra Hilliard, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E–249, Washington, DC 20202–6450. Telephone: (202) 453–6726 or by email: *deirdra.hilliard@ed.gov.*

If you use a TDD or a TTY, call the Federal Relay Service, toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: June 20, 2016.

Ann Whalen,

Senior Advisor to the Secretary, Delegated the Duties of Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2016–14907 Filed 6–22–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[FE Docket No. 16–34–LNG]

Cameron LNG, LLC; Application for Blanket Authorization To Export Liquefied Natural Gas to Non-Free Trade Agreement Nations on a Short-Term Basis

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of application.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of receipt of an application (Application), filed on February 19, 2016, by Cameron LNG, LLC (Cameron LNG), requesting blanket authorization to export liquefied natural gas (LNG) in an amount up to the equivalent of 254 billion cubic feet (Bcf) of natural gas on a cumulative basis over a two-year period effective as of the commencement of export of commissioning volumes, estimated to be the fourth quarter of 2017, but no later than six months thereafter.[1] The LNG would be exported from the Cameron Terminal located in Cameron and Calcasieu Parishes, Louisiana to any country with the capacity to import LNG in ocean-going carriers and with which trade is not prohibited by U.S. law or policy, including both countries with which the United States has entered into a free trade agreement providing for national treatment for trade in natural gas (FTA countries) and other countries (non-FTA countries).

To date, Cameron LNG has been granted 5 long-term, multi-contract authorizations from DOE/FE: (1) Order No. 3059 to export LNG in a volume equivalent to 620 Bcf per year of natural gas from the Cameron Terminal to FTA countries, for a 20-year term; (2) Order No. 3391–A to export LNG in a volume equivalent to 620 Bcf per year of natural gas from the Cameron Terminal to non-FTA countries, for a 20-year term;[2] (3) Order No. 3620 to export LNG in a volume equivalent to 152 Bcf per year of natural gas from the Cameron Terminal to FTA countries, for a 20-year term; (4) Order No. 3797 to export LNG in a volume equivalent to 152 Bcf per year of natural gas from the Cameron Terminal to non-FTA countries, for a 20-year term[3] and (5) Order No. 3680 to export LNG in a volume equivalent to 515 Bcf per year of natural gas from the Cameron Terminal to FTA countries, for a 20-year term. Cameron LNG also has submitted a pending application in DOE/FE Docket No. 15–90–LNG to export LNG in a volume equivalent to 515 Bcf per year of natural gas from the Cameron Terminal to non-FTA countries, for a 20-year term. The volume in Cameron LNG's pending application is not additive to the volume authorized in DOE/FE Order No. 3680.

Cameron LNG states that, in anticipation of the start of liquefaction operations at the Cameron Terminal, it requests this blanket authorization to engage in short-term exports of LNG produced before the commencement of long-term commercial exports of domestically sourced LNG as approved in DOE/FE Order Nos. 3059, 3391–A, 3620, 3680, and 3797.[4] Cameron LNG seeks to export this LNG on its own behalf and as agent for other parties who will hold title to the LNG at the time of export. The Application was filed under section 3 of the Natural Gas Act (NGA). Additional details can be found in Cameron LNG's Application, posted on the DOE/FE Web site at: *http://energy.gov/fe/cameron-lng-llc-fe-dkt-no-16-34-lng-application-blanket-authority-export-lng-short-term-basis-fta.*

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[1] Cameron LNG, LLC, Supplement Letter To Application to Export Liquefied Natural Gas on a Short-Term Basis to FTA and Non-FTA Countries, (Mar. 10, 2016).

[2] Order Nos. 3059 and 3391–A are not additive.

[3] Order Nos. 3620 and 3797 are not additive.

[4] DOE/FE issued Order No. 3797 after Cameron LNG filed the application in DOE/FE Docket No. 14–34–LNG. DOE/FE has included the Order because Cameron LNG referencing the docket as a pending application at 4.

Protests, motions to intervene, notices of intervention, and written comments are invited.

DATES: Protests, motions to intervene or notices of intervention, as applicable, requests for additional procedures, and written comments are to be filed using procedures detailed in the Public Comment Procedures section no later than 4:30 p.m., Eastern time, July 25, 2016.

ADDRESSES:

Electronic Filing by email: fergas@hq.doe.gov.

Regular Mail: U.S. Department of Energy (FE–34), Office of Regulation and International Engagement, Office of Fossil Energy, P.O. Box 44375, Washington, DC 20026–4375.

Hand Delivery or Private Delivery Services (e.g., FedEx, UPS, etc.): U.S. Department of Energy (FE–34), Office of Regulation and International Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT:

Larine Moore or Amy Sweeney, U.S. Department of Energy (FE–34), Office of Regulation and International Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–9478; (202) 586–2627.

Edward Myers, U.S. Department of Energy (GC–76), Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–3397.

SUPPLEMENTARY INFORMATION:

DOE/FE Evaluation

The portion of the Application seeking authority to export commissioning volumes to non-FTA countries will be reviewed pursuant to section 3(a) of the NGA, 15 U.S.C. 717b(a), and DOE will consider any issues required by law or policy. In reviewing this Application, DOE will consider domestic need for the natural gas, as well as any other issues determined to be appropriate, including whether the arrangement is consistent with DOE's policy of promoting competition in the marketplace by allowing commercial parties to freely negotiate their own trade arrangements. As part of this analysis, DOE will consider the following two studies examining the cumulative impacts of exporting domestically produced LNG:

- *Effect of Increased Levels of Liquefied Natural Gas on U.S. Energy Markets,* conducted by the U.S. Energy Information Administration upon DOE's request (2014 EIA LNG Export Study);[5] and
- *The Macroeconomic Impact of Increasing U.S. LNG Exports,* conducted jointly by the Center for Energy Studies at Rice University's Baker Institute for Public Policy and Oxford Economics, on behalf of DOE (2015 LNG Export Study).[6]

Additionally, DOE will consider the following environmental documents:

- *Addendum to Environmental Review Documents Concerning Exports of Natural Gas From the United States, 79 FR 48132 (Aug. 15, 2014);*[7] and
- *Life Cycle Greenhouse Gas Perspective on Exporting Liquefied Natural Gas from the United States,* 79 FR 32260 (June 4, 2014).[8]

Parties that may oppose this Application should address these issues and documents in their comments and/or protests, as well as other issues deemed relevant to the Application.

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.*, requires DOE to give appropriate consideration to the environmental effects of its proposed decisions. Cameron LNG states that no new or modified facilities at the Cameron Terminal would be required for the short-term exports requested in the Application. No final decision will be issued in this proceeding until DOE has met its environmental responsibilities.

Interested persons will be provided 30 days from the date of publication of this Notice in which to submit comments, protests, motions to intervene, notices of intervention, or motions for additional procedures.

Public Comment Procedures

In response to this Notice, any person may file a protest, comments, or a motion to intervene or notice of intervention, as applicable. Interested parties will be provided 30 days from the date of publication of this Notice in which to submit comments, protests, motions to intervene, or notices of intervention.

Any person wishing to become a party to the proceeding must file a motion to intervene or notice of intervention. The filing of comments or a protest with respect to the Application will not serve to make the commenter or protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the Application. All protests, comments, motions to intervene, or notices of intervention must meet the requirements specified by the regulations in 10 CFR part 590.

Filings may be submitted using one of the following methods: (1) Emailing the filing to *fergas@hq.doe.gov,* with FE Docket No. 16–34–LNG in the title line; (2) mailing an original and three paper copies of the filing to the Office of Regulation and International Engagement at the address listed in **ADDRESSES**; or (3) hand delivering an original and three paper copies of the filing to the Office of Regulation and International Engagement at the address listed in **ADDRESSES**. All filings must include a reference to FE Docket No. 16–34–LNG. **Please Note:** If submitting a filing via email, please include all related documents and attachments (*e.g.*, exhibits) in the original email correspondence. Please do not include any active hyperlinks or password protection in any of the documents or attachments related to the filing. All electronic filings submitted to DOE must follow these guidelines to ensure that all documents are filed in a timely manner. Any hardcopy filing submitted greater in length than 50 pages must also include, at the time of the filing, a digital copy on disk of the entire submission.

A decisional record on the Application will be developed through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final Opinion and Order may be issued based on the official record, including the Application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

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[5] The 2014 EIA LNG Export Study, published on Oct. 29, 2014, is available at: *https://www.eia.gov/analysis/requests/fe/.*

[6] The 2015 LNG Export Study, dated Oct. 29, 2015, is available at: *http://energy.gov/sites/prod/files/2015/12/f27/20151113_macro_impact_of_lng_exports_0.pdf.*

[7] The Addendum and related documents are available at: *http://energy.gov/fe/draft-addendum-environmental-review-documents-concerning-exports-natural-gas-united-states.*

[8] The Life Cycle Greenhouse Gas Report is available at: *http://energy.gov/fe/life-cycle-greenhouse-gas-perspective-exporting-liquefied-natural-gas-united-states.*

The Application is available for inspection and copying in the Office of Regulation and International Engagement docket room, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. The Application and any filed protests, motions to intervene or notice of interventions, and comments will also be available electronically by going to the following DOE/FE Web address: *http://www.fe.doe.gov/programs/gasregulation/index.html.*

Issued in Washington, DC, on June 16, 2016.

John A. Anderson,

Director, Office of Regulation and International Engagement, Office of Oil and Natural Gas.

[FR Doc. 2016–14869 Filed 6–22–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: U.S. Department of Energy.

ACTION: Submission for Office of Management and Budget (OMB) review; comment request.

SUMMARY: The Department of Energy (DOE) has submitted an information collection request to the OMB for extension under the provisions of the Paperwork Reduction Act of 1995. The information collection request a three-year extension for Exchange/Sale Report, Excess Personal Property Furnished to Non-Federal Recipients, Agency Report of Motor Vehicle Data, Annual Motor Vehicle Fleet Report, and OMB Control Number 1910–1000. The proposed collection covers information necessary to prepare and submit the annual property reports required by 41 CFR part 102 and the Office of Management and Budget.

DATES: Comments regarding this proposed information collection must be received on or before July 25, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, please advise the OMB Desk Officer of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at 202–395–4650.

ADDRESSES: Written comments may be sent to DOE Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, 735 17th Street NW., Washington, DC 20503.

And to: Scott Whiteford, Deputy Director Office of Asset Management, MA–50/L'Enfant Plaza Building, Washington, DC 20585–1615, *scott.whiteford@hq.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Scott Whiteford, at the above address, or by telephone at (202) 287–1563, or by fax (202) 287–1656.

Information for the Excess Personal Property Furnished to Non-Federal Recipients and the Exchange/Sale Report is collected using GSA's Personal Property Reporting Tool and can be found at the following link: *https://gsa.inl.gov/property/.*

Information for the Federal Fleet Report is collected using the Federal Automotive Statistical Tool and can be found at the following link: *https://fastweb.inel.gov/.*

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) OMB No. 1910–1000; (2) Information Collection Request Title: Exchange/Sale Report, Excess Personal Property Furnished to Non-Federal Recipients, Federal Automotive Statistical Tool Report; (3) Type of Review: Renewal; (4) Purpose: The information being collected is data required in order to submit annual personal property reports as required by 41 CFR part 102 and the Office of Management and Budget. Respondents to this information collection request will be the Department of Energy's Management and Operating Contractor and other major site contractors; (5) Annual Estimated Number of Total Respondents: 76 respondents for each of the three reports; (6) Annual Estimated Number of Total Responses: 228 (76 respondents × 3 reports) ; (7) Total annual estimated number of burden hours is 1,672. A breakout of burden hours for each report is listed below:

○ Exchange/Sale 2 hours with 76 respondents,

○ Non-Federal Recipient Report are estimated at 2 hours for 76 estimated,

○ Federal Automotive Statistical Tool at 18 hours for each of the 76 estimated respondents, for a total of 1,368 burden hours.

(8) Annual Estimated Reporting and Recordkeeping Cost Burden is $133,760.

Authority: (A) 41 CFR 102–39.85, (B) 41 CFR 102–36.295 and 102–36.300, (C) OMB Circular A–11 section 25.5, (D) 41 CFR 102–34.335.

Issued in Washington, DC, on June 17, 2016.

Scott Whiteford,

Deputy Director Office of Asset Management.

[FR Doc. 2016–14864 Filed 6–22–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–132–000.
Applicants: West Deptford Energy, LLC.
Description: Application for Approval Under Section 203 of the Federal Power Act and Request for Expedited Action of West Deptford Energy, LLC.
Filed Date: 6/16/16.
Accession Number: 20160616–5163.
Comments Due: 5 p.m. ET 7/7/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–1946–000.
Applicants: Atlantic Energy LLC.
Description: Baseline eTariff Filing: Atlantic Energy Market Based Rate Tariff to be effective 6/16/2016.
Filed Date: 6/16/16.
Accession Number: 20160616–5150.
Comments Due: 5 p.m. ET 7/7/16.

Docket Numbers: ER16–1947–000.
Applicants: Atlantic Energy MD, LLC.
Description: Baseline eTariff Filing: Atlantic Energy MD Market Based Rate Tariff to be effective 6/16/2016.
Filed Date: 6/16/16.
Accession Number: 20160616–5151.
Comments Due: 5 p.m. ET 7/7/16.

Docket Numbers: ER16–1948–000.
Applicants: Atlantic Energy MA LLC.
Description: Baseline eTariff Filing: Atlantic Energy MA Market Based Rate Tariff to be effective 6/16/2016.
Filed Date: 6/16/16.
Accession Number: 20160616–5156.
Comments Due: 5 p.m. ET 7/7/16.

Docket Numbers: ER16–1949–000.
Applicants: West Deptford Energy, LLC.
Description: Request for Waiver and Request for Expedited Consideration of West Deptford Energy, LLC.
Filed Date: 6/16/16.
Accession Number: 20160616–5170.
Comments Due: 5 p.m. ET 7/7/16.

Docket Numbers: ER16–1950–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to WMPA SA No. 3234,

Queue No. W4–060 per Assignment to CEP to be effective 9/17/2014.

Filed Date: 6/17/16.

Accession Number: 20160617–5020.

Comments Due: 5 p.m. ET 7/8/16.

Docket Numbers: ER16–1951–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 2646R2 Kansas Municipal Energy Agency NITSA NOA to be effective 6/1/2016.

Filed Date: 6/17/16.

Accession Number: 20160617–5030.

Comments Due: 5 p.m. ET 7/8/16.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES16–38–000.

Applicants: AEP Texas Central Company.

Description: Application Pursuant to Section 204 of the Federal Power Act of AEP Texas Central Company to issue securities.

Filed Date: 6/16/16.

Accession Number: 20160616–5162.

Comments Due: 5 p.m. ET 7/7/16.

Docket Numbers: ES16–39–000.

Applicants: AEP Texas North Company.

Description: Application Under Section 204 of the Federal Power Act of AEP Texas North Company to issue securities.

Filed Date: 6/16/16.

Accession Number: 20160616–5165.

Comments Due: 5 p.m. ET 7/7/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: June 17, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–14862 Filed 6–22–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1987–002.

Applicants: Ontario Power Generation Energy Trading, Inc.

Description: Notice of Non-Material Change in Status of Ontario Power Generation Energy Trading, Inc.

Filed Date: 6/17/16.

Accession Number: 20160617–5119.

Comments Due: 5 p.m. ET 7/8/16.

Docket Numbers: ER10–2137–016; ER14–2798–008; ER14–2799–008; ER16–750–004; ER12–164–015; ER15–1873–006; ER10–2130–016; ER10–2131–016; ER10–2138–016; ER10–2139–016; ER10–2140–016; ER10–2141–016; ER14–2187–010; ER11–4044–017; ER11–4046–016; ER10–2127–015; ER10–2125–016; ER16–1406–002; ER15–1041–006; ER15–2205–006; ER10–2133–016; ER10–2124–015; ER11–3872–017; ER10–2764–015; ER10–2132–015; ER10–2128–015.

Applicants: Beech Ridge Energy LLC, Beech Ridge Energy II LLC, Beech Ridge Energy Storage LLC, Bethel Wind Farm LLC, Forward Energy LLC, Bishop Hill Energy III LLC, Grand Ridge Energy LLC, Grand Ridge Energy II LLC, Grand Ridge Energy III LLC, Grand Ridge Energy IV LLC, Grand Ridge Energy V LLC, Grand Ridge Energy Storage LLC, Gratiot County Wind LLC, Gratiot County Wind II LLC, Invenergy TN LLC, Judith Gap Energy LLC, Peak View Wind Energy LLC, Prairie Breeze Wind Energy II LLC, Prairie Breeze Wind Energy III LLC, Sheldon Energy LLC, Spring Canyon Energy LLC, Stony Creek Energy LLC, Vantage Wind Energy LLC, Willow Creek Energy LLC, Wolverine Creek Energy LLC, Buckeye Wind Energy LLC.

Description: Notification of Change in Facts of Beech Ridge Energy LLC, et al.

Filed Date: 6/16/16.

Accession Number: 20160616–5175.

Comments Due: 5 p.m. ET 7/7/16.

Docket Numbers: ER14–1193–001.

Applicants: West Deptford Energy, LLC.

Description: Compliance filing: Informational Filing Regarding Planned Transfer to be effective N/A.

Filed Date: 6/17/16.

Accession Number: 20160617–5113.

Comments Due: 5 p.m. ET 7/8/16.

Docket Numbers: ER16–1637–001.

Applicants: UIL Distributed Resources, LLC.

Description: Tariff Amendment: Supplement to Application for Market-Based Rate Authorization to be effective 5/7/2016.

Filed Date: 6/17/16.

Accession Number: 20160617–5171.

Comments Due: 5 p.m. ET 7/8/16.

Docket Numbers: ER16–1833–000.

Applicants: Sempra Gas & Power Marketing, LLC.

Description: Supplement to June 1, 2016 Sempra Gas & Power Marketing, LLC tariff filing.

Filed Date: 6/16/16.

Accession Number: 20160616–5172.

Comments Due: 5 p.m. ET 7/7/16.

Docket Numbers: ER16–1952–000.

Applicants: Boulder Solar Power, LLC.

Description: Initial rate filing: Boulder Shared Facilities Agreement No. 1 to be effective 7/1/2016.

Filed Date: 6/17/16.

Accession Number: 20160617–5086.

Comments Due: 5 p.m. ET 7/8/16.

Docket Numbers: ER16–1953–000.

Applicants: Boulder Solar II, LLC.

Description: Baseline eTariff Filing: Boulder Shared Facilities Agreement No. 1 to be effective 7/1/2016.

Filed Date: 6/17/16.

Accession Number: 20160617–5088.

Comments Due: 5 p.m. ET 7/8/16.

Docket Numbers: ER16–1954–000.

Applicants: Boulder Solar III, LLC.

Description: Baseline eTariff Filing: Boulder Shared Facilities Agreement No. 1 to be effective 7/1/2016.

Filed Date: 6/17/16.

Accession Number: 20160617–5089.

Comments Due: 5 p.m. ET 7/8/16.

Docket Numbers: ER16–1955–000.

Applicants: Antelope DSR 2, LLC.

Description: Baseline eTariff Filing: Antelope DSR 2, LLC MBR Tariff to be effective 6/18/2016.

Filed Date: 6/17/16.

Accession Number: 20160617–5096.

Comments Due: 5 p.m. ET 7/8/16.

Docket Numbers: ER16–1956–000.

Applicants: Western Antelope Dry Ranch LLC.

Description: Baseline eTariff Filing: Western Antelope Dry Ranch LLC MBR Tariff to be effective 6/18/2016.

Filed Date: 6/17/16.

Accession Number: 20160617–5102.

Comments Due: 5 p.m. ET 7/8/16.

Docket Numbers: ER16–1957–000.

Applicants: Niagara Mohawk Power Corporation, New York Independent System Operator, Inc.

Description: § 205(d) Rate Filing: NMPC filing SA 2283 Commercial Agreement between NMPC & NYSEG to be effective 4/20/2016.

Filed Date: 6/17/16.

Accession Number: 20160617–5114.
Comments Due: 5 p.m. ET 7/8/16.

Docket Numbers: ER16–1958–000.
Applicants: Panda Patriot LLC.
Description: Initial rate filing: Reactive Supply and Voltage Control from Generation or Other Sources Service to be effective 7/1/2016.
Filed Date: 6/17/16.
Accession Number: 20160617–5164.
Comments Due: 5 p.m. ET 7/8/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: June 17, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–14863 Filed 6–22–16; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 10:23 a.m. on Tuesday, June 21, 2016, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters related to the Corporation's supervision, corporate, and resolution activities.

In calling the meeting, the Board determined, on motion of Vice Chairman Thomas M. Hoenig, seconded by Director Thomas J. Curry (Comptroller of the Currency), concurred in by Director Richard Cordray (Director, Consumer Financial Protection Bureau), and Chairman Martin J. Gruenberg, that Corporation business required its consideration of the matters which were to be the subject of this meeting on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10).

Dated: June 21, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–14996 Filed 6–21–16; 4:15 pm]

BILLING CODE P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

AGENCY: Federal Election Commission.

DATE & TIME: Tuesday, June 28, 2016 at 10:00 a.m.

PLACE: 999 E Street NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 52 U.S.C. 30109.

Matters concerning participation in civil actions or proceeding, or arbitration.

* * * * *

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Shawn Woodhead Werth,

Secretary and Clerk.

[FR Doc. 2016–15028 Filed 6–21–16; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than July 11, 2016.

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Brian Scott Curb, Bemidji, MN; Melisa A. Bruns, Bemidji, MN; Ronald R. Cuperus, Bemidji, MN; Dean J. Thompson, Bemidji, MN; Glen T. Lindseth, Bemidji, MN; Mary Karen Bellmont Revocable Trust (Mary Karen Bellmont, trustee), St. Cloud, MN; Robert C. Welle Living Trust (Robert C. Welle, trustee), Saint Paul, MN; John P. Welle, Granger, IN; Mary Kay Welle, Granger, IN; Margaret M. Sitzer Revocable Trust (Margaret M. Sitzer, trustee), Rochester, MN; Patrick G. Welle, Bemidji, MN; Peter T. Welle, Washington, DC; Susan M. Stromberg, Colorado Springs, CO; Michael M. Stromberg, Colorado Springs, CO; David M. Stromberg, Grand Forks, ND; Brian W. Stromberg, Grand Forks, ND; Megan E. Stromberg, Grand Forks, ND; Theresa A. Welle, Waite Park, MN; Mary J. Welle Marvin, Warroad, MN; Conway A. Marvin, Warroad, MN; Nicholas A. Marvin, Warroad, MN; Ryan W. Marvin, Minneapolis, MN; Laura J. Marvin Nelson, Eden Prairie, MN; Jackelyn L. Marvin, Bemidji, MN; Christian D. Welle, Bemidji, MN; Amanda B. Welle, New York, NY; Jamie M. Welle, Lonsdale, MN; Samantha J. Baker, Bemidji, MN; Joseph W. Welle, Bloomington, MN; Katherine L. Canfield, Pinehurst, NC; Brian T. Canfield, Pinehurst, NC; William RW Canfield, Pinehurst, NC; Sarah J. Anderla, Appleton, WI; David Anderla, Appleton, WI; Drew B. Anderla, Appleton, WI; and Sarah J. Anderla, as custodian for Grant T. Anderla, Appleton, WI, and as custodian for Elena J. Anderla, Appleton, WI;* for retroactive approval to join the Welle family shareholder group that controls 25 percent or more of the voting shares of First Bemidji Holding Company, Bemidji, Minnesota, and thereby indirectly controls The First National Bank of Bemidji, Bemidji, Minnesota.

Board of Governors of the Federal Reserve System, June 20, 2016.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2016–14861 Filed 6–22–16; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1548]

Invitation To Participate in Account Management Pilot for the Import Trade Auxiliary Communication System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it intends to conduct a pilot program to test and evaluate a new Import Trade Auxiliary Communication System (ITACS) Account Management function. Participation will be needed from a small group of Filers, Importers of Record, and Consignees, who will use the new ITACS Account Management function and provide feedback to FDA. FDA is inviting individual firms that wish to participate in this pilot program to submit participation requests via email.

DATES: To be considered for participation in this ITACS pilot, please send an email with the subject line "ITACS Pilot Participation Request" by July 7, 2016.

ADDRESSES: Submit pilot participation request emails to FDA's ITACS Support at *itacssupport@fda.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Sandra Abbott, Division of Compliance Systems, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20852–1740, 301–796–3240, *itacssupport@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

ITACS currently provides the import trade community with four functions: (1) The ability to check the status of FDA-regulated entries and lines, (2) the ability to submit entry documentation electronically, (3) the ability to electronically submit the location of goods availability for those lines targeted for FDA physical examination, and (4) the ability to check the estimated laboratory analysis completion dates. No user login accounts are necessary to access these functions; all that is necessary is a valid customs entry number that has been successfully transmitted to FDA. FDA has developed, and wishes to test, an ITACS user account management function.

II. Description and Conditions of the Pilot Program

The purpose of this pilot is to test and evaluate a new ITACS account management function.

This pilot will not impact the availability of current functionality of ITACS. Rather, it will provide FDA and a small group of volunteers with the opportunity to test expanded functionality of ITACS, specifically the use of user login accounts. User login accounts enable FDA to distribute Notices of FDA Action to users electronically via email (rather than regular mail) and enable users to download Notices of FDA Action from within ITACS. User login accounts also allow users to view in ITACS the details of specific information requests, which are currently delivered via hard copy Notices of FDA Action. Implementation of user login accounts would also allow for potential future ITACS enhancements, requested by the import trade community, that require user authentication.

Pilot participants should be prepared to commit to: (1) Attending a kickoff training session, using the new functionality, (2) providing real-time feedback, and (3) participating in any followup meetings FDA deems necessary over the course of the pilot period. Pilot participants should also be willing to receive their Notices of FDA Action electronically in lieu of FDA distribution of paper Notices of FDA action.

III. Duration

FDA currently anticipates the pilot to begin in July 2016 and to last through October 2016. However, these dates are subject to change. A more definitive schedule will be determined after FDA has selected volunteers. FDA will contact selected volunteers via email within 2 weeks of the closure of the solicitation period.

IV. How To Apply for Participation in the Pilot

To be considered for participation in this ITACS pilot, please send an email with the subject line "ITACS Pilot Participation Request" to *itacssupport@fda.hhs.gov* by July 7, 2016. Please limit participation requests to one individual per firm at the corporate level. That person should be a high-ranking individual within the firm who could have the capability to create and manage ITACS accounts for other users at different locations within the same firm. FDA expects to select nine or fewer participants for this pilot program.

Please include the following information in your pilot participation request email:

- Your name, position, and contact information including email;
- your firm's name and address; and
- your firm's role in the importation of FDA-regulated entries (Filer, Importer of Record, Consignee, or any combination thereof).

FDA will contact volunteers selected for participation in the pilot program via email within 2 weeks of the closure of the solicitation period.

Dated: June 17, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–14874 Filed 6–22–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of June 16, 2016. The amendment is being made to reflect a change in the *Procedure* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Lauren D. Tesh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *ODAC@fda.hhs.gov;* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 16, 2016, 81 FR 39274, FDA announced that a meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee would be held on June 28 and 29, 2016. On page 39274, in the third column, the *Procedure* portion of the document is changed to read as follows:

FDA regrets that it was unable to publish this notice 15 days prior to the June 28 and 29, 2016, Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee meeting. Because the Agency believes there is some urgency to bring these issues to public discussion and qualified members of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee meeting were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: June 16, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–14827 Filed 6–22–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1280]

International Conference on Harmonisation; Electronic Transmission of Postmarket Individual Case Safety Reports for Drugs and Biologics, Excluding Vaccines; Availability of Food and Drug Administration Regional Implementation Specifications for ICH E2B(R3) Reporting to the Food and Drug Administration Adverse Event Reporting System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of its FDA Adverse Event Reporting System (FAERS) Regional Implementation Specifications for the International Conference on Harmonisation (ICH) E2B(R3) Specification. FDA is making this technical specifications document available to assist interested parties in electronically submitting individual case safety reports (ICSRs) (and ICSR attachments) to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). This document, entitled "FDA Regional Implementation Specifications for ICH E2B(R3) Implementation: Postmarket Submission of Individual Case Safety Reports (ICSRs) for Drugs and Biologics, Excluding Vaccines" supplements the "E2B(R3) Electronic Transmission of Individual Case Safety Reports (ICSRs) Implementation Guide—Data Elements and Message Specification" final guidance for industry and describes FDA's technical approach for receiving ICSRs, for incorporating regionally controlled terminology, and for adding region-specific data elements when reporting to FAERS.

DATES: Submit either electronic or written comments on the Regional Implementation Specifications document at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–D–1280 for "FDA Regional Implementation Specifications for ICH E2B(R3) Implementation: Postmarket Submission of Individual Case Safety Reports for Drugs and Biologics, Excluding Vaccines." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Suranjan De, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4307, Silver Spring, MD 20993, 240–402–0498, or *FAERSESUB@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

On February 21, 2014, FDA issued a **Federal Register** notice (79 FR 9908) announcing the availability of a final guidance for industry entitled "E2B (R3) Electronic Transmission of Individual Case Safety Reports (ICSRs) Implementation Guide—Data Elements and Message Specification" (ICH E2B(R3) guidance) and an appendix to the guidance entitled "ICSRs: Appendix to the Implementation Guide—Backwards and Forward Compatibility" (BFC appendix). The ICH E2B(R3) guidance and BFC appendix were issued as a package that included schema files and additional technical information to be used for creating compatible ICSR files. The preface to the ICH E2B(R3) implementation guidance makes clear that any future "technical specifications document associated with that guidance would be provided as a stand-alone document" but incorporated by reference into that guidance. Accordingly, in this notice, we are announcing the availability of a technical specifications document that will be incorporated into that final guidance.

This technical specifications document, which is available on the FDA Guidance Web page at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm274966.htm,* is to assist interested parties in electronically submitting individual case safety reports (ICSRs) (and any ICSR attachments) to CDER and CBER. This document describes FDA's technical approach for submitting ICSRs, for incorporating its regionally controlled terminology, and for adding its regional data elements that are not addressed in the ICH E2B (R3) guidance for the following FDA-regulated products: Drug products marketed for human use with approved new drug applications and abbreviated new drug applications; prescription drug products marketed for human use without an approved application; nonprescription (over-the-counter) human drug products marketed without an approved application; and biological products marketed for human use with approved biologic license applications.

II. Electronic Access

Persons with access to the Internet may obtain a copy of the FDA Regional Implementation Specifications for ICH E2B(R3) at *http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/adversedrugeffects/ucm115894.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov.*

Dated: June 17, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–14845 Filed 6–22–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–0374]

Waterway Suitability Assessment for Construction and Operation of Liquefied Gas Terminals; Sabine-Neches Waterway, Vidor, TX

AGENCY: Coast Guard, DHS.

ACTION: Notice and request for comments.

SUMMARY: Jefferson Railport Terminal 1 (Texas) LLC, has submitted a Letter of Intent and Preliminary Waterway Suitability Assessment to the Coast Guard Captain of the Port (COTP), Port Arthur, TX regarding the company's plans to construct, own and operate a waterfront facility handling and storing Liquefied Hazardous Gas (LHG) at its Vidor, TX facility located on the Sabine-Neches Waterway. The Coast Guard is notifying the public of this action to solicit public comments on the proposed increase in LHG marine traffic on the Sabine-Neches Waterway.

DATES: Comments must be submitted to the online docket via *http://www.regulations.gov,* or reach the Docket Management Facility, on or before July 25, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0374 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: For further information about this notice, call or email Chief Petty Officer Jamie L. Merriman, U.S. Coast Guard; telephone 409–719–5033, email *jamie.l.merriman@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Public Participation and Comments

We encourage you to submit comments or related material in response to this notice. We will consider all submissions and may adjust our final action based on your comments. If you submit a comment, please include the docket number for this notice, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Discussion, Basis, and Purpose

Under 33 CFR 127.007(a), an owner or operator planning to build a new facility handling Liquefied Natural Gas (LNG) or Liquefied Hazardous Gas (LHG), where the construction, expansion, or modification would result in an increase in the size and/or frequency of LNG or LHG marine traffic on the waterway associated with the facility, must submit a Letter of Intent (LOI) to the COTP of the zone in which the facility is located. Under 33 CFR 127.007(e), an owner or operator planning such an expansion must also file or update a Waterway Suitability Assessment (WSA) that addresses the proposed increase in LNG or LHG marine traffic in the associated waterway. Jefferson Railport Terminal 1 (Texas) LLC, located in Vidor, TX submitted an LOI and WSA on March 7, 2016, regarding the company's proposed construction and operation of LHG capabilities at its Vidor, TX facility.

Under 33 CFR 127.009, after receiving an LOI, the COTP issues a Letter of Recommendation (LOR) as to the suitability of the waterway for LNG or LHG marine traffic to the appropriate jurisdictional authorities. The LOR is based on a series of factors outlined in 33 CFR 127.009 that relate to the physical nature of the affected waterway and issues of safety and security associated with LNG or LHG marine traffic on the affected waterway.

The purpose of this notice is to solicit public comments on the proposed increase in LHG marine traffic on the Sabine-Neches Waterway. The Coast Guard believes that input from the public may be useful to the COTP with respect to development of the LOR. Additionally, the Coast Guard intends to task the Area Maritime Security Committee, Port Arthur, TX and the Southeast Texas Waterways Advisory Council with forming a subcommittee comprised of affected port users and stakeholders. The goal of this subcommittee will be to gather information to help the COTP assess the suitability of the associated waterway for increased LHG marine traffic as it relates to navigational safety and security.

On January 24, 2011, the Coast Guard published Navigation and Vessel Inspection Circular (NVIC) 01–2011, "Guidance Related to Waterfront Liquefied Natural Gas (LNG) Facilities". NVIC 01–2011 provides guidance for owners and operators seeking approval to build and operate LNG facilities. While NVIC 01–2011 is specific to LNG, it provides useful process information and guidance for owners and operators seeking approval to build and operate LHG facilities as well. The Coast Guard will refer to NVIC 01–2011 for process information and guidance in evaluating Jefferson Railport Terminal 1's WSA. A copy of NVIC 01–2011 is available for viewing in the public docket for this notice and also on the Coast Guard's Web site at *http://www.uscg.mil/hq/cg5/nvic/2010s.asp.*

This notice is issued under authority of 33 U.S.C. 1223–1225, Department of Homeland Security Delegation Number 0170.1(70), 33 CFR 127.009, and 33 CFR 103.205.

Dated: May 27, 2016.

R.S. Ogrydziak,

Captain, U.S. Coast Guard, Captain of the Port, Port Arthur.

[FR Doc. 2016–14910 Filed 6–22–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0111]

Agency Information Collection Activities: Arrival and Departure Record (Forms I–94 and I–94W) and Electronic System for Travel Authorization

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; revision of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: CBP Form I–94 (Arrival/Departure Record), CBP Form I–94W (Nonimmigrant Visa Waiver Arrival/Departure), and the Electronic System for Travel Authorization (ESTA). This is a proposed extension and revision of an information collection that was previously approved. CBP is proposing that this information collection be extended with a revision to the information collected. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before August 22, 2016 to be assured of consideration.

ADDRESSES: Written comments may be mailed to U.S. Customs and Border Protection, Attn: Paperwork Reduction Act Officer, Regulations and Rulings, Office of Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Regulations and Rulings, Office of Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, or by telephone at 202–325–0123.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: Arrival and Departure Record, Nonimmigrant Visa Waiver Arrival/Departure, and Electronic System for Travel Authorization (ESTA).

OMB Number: 1651–0111.

Form Numbers: I–94 and I–94W.

Abstract

Background

CBP Forms I–94 (Arrival/Departure Record) and I–94W (Nonimmigrant Visa Waiver Arrival/Departure Record) are used to document a traveler's admission into the United States. These forms are filled out by aliens and are used to collect information on citizenship, residency, passport, and contact information. The data elements collected on these forms enable the Department of Homeland Security (DHS) to perform its mission related to the screening of alien visitors for potential risks to national security and the determination of admissibility to the United States. The Electronic System for Travel Authorization (ESTA) applies to aliens seeking to travel to the United States under the Visa Waiver Program (VWP) and requires that VWP travelers provide information electronically to CBP before embarking on travel to the

United States without a visa. Travelers who are entering the United States under the VWP in the air or sea environment, and who have a travel authorization obtained through ESTA, are not required to complete the paper Form I–94W.

Pursuant to an interim final rule published on March 27, 2013 in the **Federal Register** (78 FR 18457) related to Form I–94, CBP has partially automated the Form I–94 process. CBP now gathers data previously collected on the paper Form I–94 from existing automated sources in lieu of requiring passengers arriving by air or sea to submit a paper I–94 upon arrival. Passengers can access and print their electronic I–94 via the Web site at *www.cbp.gov/I94.*

ESTA can be accessed at: *https://esta.cbp.dhs.gov.* Samples of CBP Forms I–94 and I–94W can be viewed at: *http://www.cbp.gov/document/forms/form-i-94-arrivaldeparture-record* and *http://www.cbp.gov/document/forms/form-i-94w-visa-waiver-arrivaldeparture-record.*

Recent Changes

On December 18, 2015, the President signed into law the Visa Waiver Program Improvement and Terrorist Travel Prevention Act of 2015 as part of the Consolidated Appropriations Act of 2016. To meet the requirements of this new Act, DHS strengthened the security of the VWP by enhancing the ESTA application and Form I–94W. In two recent emergency submissions under the Paperwork Reduction Act, additional questions were added to ESTA and to Form I–94W that request information from applicants about countries to which they have traveled on or after March 1, 2011; countries of which they are citizens/nationals; countries for which they hold passports; and Global Entry Numbers.

Proposed Changes

DHS proposes to add the following question to ESTA and to Form I–94W: "Please enter information associated with your online presence—Provider/Platform—Social media identifier." It will be an optional data field to request social media identifiers to be used for vetting purposes, as well as applicant contact information. Collecting social media data will enhance the existing investigative process and provide DHS greater clarity and visibility to possible nefarious activity and connections by providing an additional tool set which analysts and investigators may use to better analyze and investigate the case.

Current Actions: This submission is being made to extend the expiration date with a change to the information collected as a result of adding a question about social media to ESTA and to Form I–94W, as described in the Abstract section of this document. There are no changes to the burden hours or to the information collected on Form I–94, or the I–94 Web site.

Type of Review: Revision.

Affected Public: Individuals, Carriers, and the Travel and Tourism Industry.

Form I–94 (Arrival and Departure Record):

Estimated Number of Respondents: 4,387,550.

Estimated Time per Response: 8 minutes.

Estimated Burden Hours: 583,544.

Estimated Annual Cost to Public: $26,325,300.

I–94 Web site:

Estimated Number of Respondents: 3,858,782.

Estimated Time per Response: 4 minutes.

Estimated Annual Burden Hours: 254,679.

Form I–94W (Nonimmigrant Visa Waiver Arrival/Departure):

Estimated Number of Respondents: 941,291.

Estimated Time per Response: 16 minutes.

Estimated Annual Burden Hours: 251,325.

Estimated Annual Cost to the Public: $5,647,746.

Electronic System for Travel Authorization (ESTA):

Estimated Number of Respondents: 23,010,000.

Estimated Time per Response: 23 minutes.

Estimated Total Annual Burden Hours: 8,812,830.

Estimated Annual Cost to the Public: $265,020,000.

Dated: June 20, 2016,

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2016–14848 Filed 6–22–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5651–N–03]

Tribal Government-to-Government Consultation Policy

AGENCY: Office of the Secretary, HUD.

ACTION: Notice of final policy statement.

SUMMARY: In compliance with Executive Order 13175, "Consultation with Indian Tribal Governments," HUD adopts this Tribal Government-to-Government Consultation Policy. The purpose of this tribal consultation policy is to enhance communication and coordination between HUD and federally recognized Indian tribes and to outline guiding principles and procedures under which all HUD employees are to operate with regard to federally recognized Indian or Alaska Native tribes. This final policy statement follows publication of an April 8, 2015, request for public comment on HUD's proposed Tribal Consultation Policy and, after consideration of the public comments submitted in response to the April 8, 2015, notice, adopts the proposed policy without change.

FOR FURTHER INFORMATION CONTACT: Heidi J. Frechette, Deputy Assistant Secretary for Native American Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4126, Washington, DC 20410, telephone number 202–401–7914 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number via TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Executive Order 13175 (65 FR 67249, published November 9, 2000) recognizes the right of Indian tribes to self-government and supports tribal sovereignty and self-determination. Among other things, it requires that agencies have an accountable process to ensure meaningful and timely input by tribal officials in developing policies that have tribal implications. On November 5, 2009, President Obama reaffirmed the government-to-government relationship between the Federal Government and Indian tribal governments in a White House memorandum that acknowledges that Indian tribes exercise inherent sovereign powers over their members and territory. The November 5, 2009, memorandum also acknowledged that the United States will continue to work with Indian tribes on a government-to-government basis to address issues concerning Indian tribal self-government, tribal trust resources, and Indian tribal treaty and other rights.

Development of HUD Tribal Government-to-Government Consultation Policy

Consistent with Executive Order 13175, and the Presidential memorandum of November 5, 2009, HUD undertook a series of consultations and requested public comment on this consultation policy statement. Beginning in January 2010, HUD held a series of HUD-tribal regional consultations to discuss HUD's existing tribal consultation policy. Each consultation session was hosted by one of the six Office of Native American Programs (ONAP) Area Office Administrators. Prior to all meetings, the ONAP Area Office sent out invitation letters to all tribes and tribally designated housing entities to inform them of the meetings. The invitation package included the President's memorandum, Executive Order 13175, HUD's current tribal consultation policy, and a list of questions designed to prompt discussion and focus on the issues. HUD's Deputy Assistant Secretary for ONAP attended a Northwest ONAP and Eastern/Woodlands ONAP session, and HUD's Assistant Secretary for Public and Indian Housing participated in the initial session held in Suquamish, Washington. Participants at each of the consultation sessions were informed that an electronic mailbox had been established to receive their comments and that HUD's CODETALK Web site would be used to display all comments received. The comments from participants who attended these consultations, as well as all comments received by other means, were consolidated by HUD's ONAP. HUD carefully reviewed all comments received from all sources, responded, and made changes to the existing HUD consultation policy based on these comments, as appropriate.

HUD conducted a second round of tribal consultation by sending the revised draft policy to all tribal leaders for their comment. On November 12, 2014, the Department provided all tribal leaders a draft version of HUD's revised tribal government-to-government consultation policy and requested their feedback and opinion on the draft. In response to the Department's November 12, 2014, request for comments, the Department received three comments from Indian tribes and a national organization that represents the housing interests of Native Americans.

More recently, on April 8, 2015, at 70 FR 18858, HUD published a **Federal Register** notice requesting public comment on its tribal government-to-government consultation policy. HUD published this notice consistent with Executive Order 13175 and a November 5, 2009, Presidential memorandum that reaffirms the government-to-government relationship between the Federal Government and Indian tribal governments. HUD received eight public comments on the notice. Comments were received from tribes and tribal housing authority officials, nonprofits, advocacy groups, and interested members of the public. After considering public comment, HUD decided not to make any changes to its draft policy published on April 8, 2015. As a result, this notice establishes HUD's Tribal Government-to-Government Consultation Policy. HUD would like to respond, however, to several comments received in response to its April 8, 2015, request for comments.

Comment: Consultation Requires Negotiated Rulemaking. One commenter stated that the consultation policy should recognize that any changes to regulations that directly impact tribes or tribal members require negotiated rulemaking. According to the commenter, there have been changes to regulations that had a direct, negative impact upon tribal members, and the only consultation performed was a "Dear Tribal Leader" letter. The commenter stated that the new consultation policy should prevent those lapses in the future by enshrining a mandatory negotiated rulemaking prior to these kinds of changes.

HUD Response: HUD disagrees that negotiated rulemaking is required for all of HUD's regulatory actions that impact the tribes. Rather, section 106 of the Native American Housing and Self-Determination Act (NAHASDA), as amended, limits negotiated rulemaking to "any regulation that may be required pursuant to requirements made to [NAHASDA] after the effective date of enactment of this Act [October 1, 2008]." See 25 U.S.C. 4116(b). Procedures for implementing this requirement were recently codified in 24 CFR 1000.9. As a result, while negotiated rulemaking is required under the Indian Housing Block Grant program, HUD believes that negotiated rulemaking is only one method of tribal consultation, and that there are other forms of consultation that ensure tribal participation in HUD policy that might affect the tribes.

Comment: Policy Should Make Clear that Tribes Can Initiate Consultation. One commenter stated that the policy as written only addresses the initiation of consultation by HUD and does not address the ability of tribes to initiate consultation with HUD on any specific issue or proposed policy that has tribal implications. The commenter recommended that the policy be revised to clarify that tribes can initiate consultation and that this right in no way alleviates HUD's regular and ongoing obligation to initiate and engage in meaningful consultation with individual tribes.

HUD Response: HUD agrees with the commenter that consultation can be initiated by the tribes. HUD is not making this change, however, since nothing in this consultation policy prevents tribe from contacting or initiating consultation with HUD.

Comment: Policy Must Address Confidentiality of Tribal Interests. One commenter, citing *Pueblo of Sandia* v *United States*, 50 F.3d 856, 861–62 (10th Cir. 1995), stated that it is critical to engage in tribal consultation in a manner that exhibits sensitivity to and respect for tribal confidentiality concerns regarding cultural, religious, political, and other intra-tribal affairs. According to the commenter, the current draft policy does not contain any provision to address the confidentiality of tribal interests. As a result, the commenter recommended that the policy be revised to require that HUD develop appropriate safeguards and policies to ensure adequate protection of tribal confidentiality interests throughout the entire consultation process.

HUD Response: HUD appreciates the comment and shares the commenter's concerns regarding the importance of ensuring the confidentiality of tribal interests when appropriate. HUD also believes, however, that consultation and collaboration as envisioned by Executive Order 13175 and the Presidential memorandum of November 5, 2009, require transparency and fairness with all tribes to build trust among the tribes and the Federal Government. Notwithstanding, HUD will be sensitive to tribal confidentiality interests throughout the entire consultation policy.

HUD Tribal Government-to-Government Consultation Policy

I. Introduction

A. The United States Government has a unique relationship with American Indian governments as set forth in the Constitution of the United States, treaties, statutes, judicial decisions, and Executive orders and Presidential memorandums.

B. On April 29, 1994, a Presidential memorandum was issued reaffirming the Federal Government's commitment to operate within a government-to-government relationship with federally recognized American Indian and Alaska Native tribes, and to advance self-governance for such tribes.[1] The Presidential memorandum directs each executive department and agency, to the greatest extent practicable and to the extent permitted by law, to consult with tribal governments prior to taking actions that have substantial direct affect on federally recognized tribal governments. In order to ensure that the rights of sovereign tribal governments are fully respected, all such consultations are to be open and candid so that tribal governments may evaluate for themselves the potential impact of relevant proposals.

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[1] See *http://www.gpo.gov/fdsys/pkg/FR-1994-05-04/html/94-10877.htm.*

On May 14, 1998, Executive Order 13084, *Consultation and Coordination with Indian Tribal Government* was issued.[2] This Executive order was revoked and superseded on November 6, 2000, by Executive Order 13175,[3] which is identically titled to Executive Order 13084 and which sets forth guidelines for all Federal agencies to: (1) Establish regular and meaningful consultation and collaboration with Indian tribal officials in the development of Federal policies that have tribal implications, (2) strengthen the United States government-to-government relationships with Indian tribes, and (3) reduce the imposition of unfunded mandates upon Indian tribes.

On November 5, 2009,[4] President Obama issued a memorandum to the heads of all executive departments and agencies that reaffirmed that the United States has a unique legal and political relationship with Indian tribal governments, established through and confirmed by the Constitution of the United States, treaties, statutes, Executive orders, and judicial decisions. The memorandum stated that in recognition of that special relationship, pursuant to Executive Order 13175, of November 6, 2000, executive departments and agencies are charged with engaging in regular and meaningful consultation and collaboration with tribal officials in the development of Federal policies that have tribal implications, and are responsible for strengthening the government-to-government relationship between the United States and Indian tribes. The memorandum stated that the Administration is committed to regular and meaningful consultation and collaboration with tribal officials in policy decisions that have tribal implications, and directed, among other things, as an initial step, through complete and consistent implementation of Executive Order 13175.

C. This consultation policy applies to all HUD programs and policies that have substantial direct effects on Federally recognized Indian tribal governments. In formulating or implementing such policies, HUD will be guided by the fundamental principles set forth in section 2 of Executive Order 13175, to the extent applicable to HUD programs. Section 2 of the Executive order provides as follows:

Sec. 2. Fundamental Principles. In formulating or implementing policies that have tribal implications, agencies shall be guided by the following fundamental principles:

(a) The United States has a unique legal relationship with Indian tribal governments as set forth in the Constitution of the United States, treaties, statutes, Executive Orders, and court decisions. Since the formation of the Union, the United States has recognized Indian tribes as domestic dependent nations under its protection. The Federal Government has enacted numerous statutes and promulgated numerous regulations that establish and define a trust relationship with Indian tribes.

(b) Our Nation, under the law of the United States, in accordance with treaties, statutes, Executive Orders, and judicial decisions, has recognized the right of Indian tribes to self-government. As domestic dependent nations, Indian tribes exercise inherent sovereign powers over their members and territory. The United States continues to work with Indian tribes on a government-to-government basis to address issues concerning Indian tribal self-government, tribal trust resources, and Indian tribal treaty and other rights.

(c) The United States recognizes the right of Indian tribes to self-government and supports tribal sovereignty and self-determination.

II. Definitions

A. "*Consultation*" means the *direct* and *interactive* (*i.e.*, collaborative) involvement of tribes in the development of regulatory policies on matters that have tribal implications.

Consultation is the proactive, affirmative process of: (1) Identifying and seeking input from appropriate Native American governing bodies, community groups, and individuals; and (2) considering their interest as a necessary and integral part of HUD's decisionmaking process.

This definition adds to statutorily mandated notification procedures. The goal of notification is to provide an opportunity for comment; however, with consultation procedures, the burden is on the Federal agency to show that it has made a good faith effort to elicit feedback.

B. "*Exigent situation*" means an unforeseen combination of circumstances or the resulting state that calls for immediate action in order to preserve tribal resources, rights, interests, or Federal funding.

C. "*Indian tribe*" means an Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.

D. "*Policies that have tribal implications*" refers to regulations, legislative proposals, and other policy statements or actions that have substantial direct effects on one or more Indian tribe, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. "*To the extent practicable and permitted by law*" refers to situations where the opportunity for consultation is limited because of constraints of time, budget, legal authority, etc.

F. "*Tribal officials*" means elected or duly appointed officials of Indian tribal governments or authorized intertribal organizations.

III. Principles

A. HUD respects tribal sovereignty and acknowledges the unique relationship between the Federal Government and Indian tribes.

B. HUD recognizes and commits to a government-to-government relationship with federally recognized tribes.

C. HUD recognizes tribes as the appropriate non-Federal parties for making policy decisions and managing programs for their constituents.

D. HUD shall take appropriate steps to remove existing legal and programmatic impediments to working directly and effectively with tribes on programs administered by HUD.

E. HUD shall encourage States and local governments to work with and cooperate with tribes to resolve problems of mutual concern.

F. HUD shall work with other Federal departments and agencies to enlist their interest and support in cooperative efforts to assist tribes to accomplish their goals within the context of all HUD programs.

G. HUD shall be guided by these policy principles in its planning and management activities, including its budget, operating guidance, legislative initiatives, management accountability system, and ongoing policy and regulation development processes for all programs affecting tribes.

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[2] See *http://www.gpo.gov/fdsys/pkg/FR-1998-05-19/pdf/98-13553.pdf.*

[3] See *http://www.gpo.gov/fdsys/pkg/FR-2000-11-09/pdf/00-29003.pdf.*

[4] See *http://www.whitehouse.gov/the-press-office/memorandum-tribal-consultation-signed-president.*

IV. Tribal Consultation Process

A. *Applicability.* HUD will apply this tribal consultation policy to all proposed policies that have tribal implications, to the greatest extent practicable and permitted by law. Based on a government-to-government relationship and in recognition of the uniqueness of each tribe, the primary focus for consultation activities is with individual tribes. The Office of Public and Indian Housing's ONAP, may serve, under the direction of the Secretary, as the lead HUD office for the implementation of this policy. Internal HUD policies and procedures are excluded from this policy.

B. *Methods of Communication.* The methods of communication used will be determined by the significance of the consultation matter, the need to act quickly, and other relevant factors. Consultation can be accomplished through various methods of communication. While modern technology and group events should be utilized whenever possible to conserve funds and respect time constraints of all those involved, generally these methods of communication should not serve in the place of formal, face-to-face discussion.

C. *Consultation with Tribes When Drafting Policies That Have Tribal Implications.* To the extent practicable and permitted by law, HUD shall make reasonable efforts to consult with tribal officials concerning proposed policies that have tribal implications, before such policies are drafted, in order to facilitate greater tribal participation in development of the proposed policies. Such consultation shall include on the HUD Web site a notice of HUD's plans to develop such policies, and an invitation for tribal officials to comment on items that should be included in such policies. HUD shall provide a specific deadline for comments, which shall not be less than 30 days from the date of the notice. This timeline may be compressed in exigent situations.

D. *Notice of Proposed Policies That Have Tribal Implications.* To the extent practicable and permitted by law, after proposed policies that have tribal implications have been drafted, HUD will notify the tribes of such proposed policies and will include a copy of the proposed policies with the notice. The notice shall designate the lead office in HUD Headquarters. The lead office in HUD Headquarters shall be responsible for such notification, unless it has delegated such responsibility to another office. HUD shall provide a specific deadline for tribal comments, which shall not be less than 60 days from the date of the notice. This timeline may be compressed in exigent situations. Nothing herein shall affect the deadlines established by Federal law or regulation with regard to comments in the course of the formal agency rulemaking process for the promulgation of Federal regulations.

E. *Tribal Response.* Tribal officials may provide recommendations concerning proposed policies that have or that may have tribal implications to the lead office in HUD Headquarters no later than the deadline established in Part IV.D of this consultation policy. Such recommendations may be provided orally during meetings with HUD representatives or by written documents submitted to HUD representatives.

F. *Meetings.* Tribes may facilitate regional meetings with HUD representatives to identify and address issues relevant to HUD policies that have tribal implications. HUD will convene at least one national tribal consultation meeting each year. To reduce costs and conserve resources to the greatest extent feasible, tribes and HUD will coordinate consultation meetings with other regularly scheduled meetings, such as multi-agency and association meetings.

G. *Reporting Mechanisms.* In all cases when a tribe or tribes have been involved in the consultation process, HUD will maintain an Internet Web site or Web page to address the informational needs of tribes and tribal leaders. Such Web site or Web page will include relevant HUD documents and other relevant documents, including comments submitted by other tribes. HUD shall notify the tribes of the finalization of proposed policies that have tribal implications, and provide such policies to the tribes.

H. *Tribal Advisory Organizations, Committees, and Workgroups.* HUD will work with tribal organizations, committees, or workgroups, when appropriate, to assist in facilitating involvement of tribes in decisionmaking and policy development. The work with tribal organizations, committees, and workgroups will be in coordination with, and not to the exclusion of, consultation with individual tribes on a government-to-government basis.

I. *Joint Federal/Tribal Workgroups.*

1. A workgroup may be established by HUD and tribes to address specific issues or to draft specific policies that have tribal implications. Tribal representation should be consistent with the established standard of geographically diverse small, medium, and large tribes, whenever possible.
2. Alternate workgroup members may be appointed by written notification signed by the member. Such alternates shall possess the authority of the workgroup member to make decisions on their behalf, if such authority is so delegated to them in writing.
3. The workgroup shall be chaired by at least one tribal workgroup member, selected by the tribal workgroup members, and one HUD representative.
4. The workgroup may conduct its activities through various methods of communication, including in-person meetings, conference calls, and Internet-based meeting platforms. Workgroup members may be accompanied by other individuals for advice, as the members deem necessary.
5. Whenever possible, workgroup products should be circulated to tribal leaders for review and comment.
6. All final recommendations will be given serious consideration by HUD.

V. Tribal Standing Committee

On issues relating to tribal self-governance, tribal trust resources, or treaty and other rights, HUD will explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking. HUD may establish a standing committee, consisting of representatives of tribal governments, to consult on the appropriateness of using negotiated rulemaking procedures on particular matters. The procedures governing such a standing committee would be established through the mutual agreement of HUD and tribal governments.

VI. Unfunded Mandates

To the extent practicable and permitted by law, HUD shall not promulgate any regulation that is not required by statute, that has tribal implications, and that imposes substantial direct compliance costs on such communities, unless:

A. Funds necessary to pay the direct costs incurred by the Indian tribal government in complying with the regulation are provided by the Federal Government; or

B. HUD, prior to the formal promulgation of the regulation:

1. Consulted with tribal officials early in the process of developing the proposed regulation;
2. In a separately identified portion of the preamble to the regulation as it is to be issued in the **Federal Register**, provides to the Director of the Office of Management and Budget (OMB) a description of the extent of HUD's prior

consultation with representatives of affected Indian tribal governments, a summary of the nature of their concerns, and the agency's position supporting the need to issue the regulation; and

3. Makes available to the Director of OMB any written communications submitted to HUD by such Indian tribal governments.

VII. Increasing Flexibility for Indian Tribal Waivers

HUD shall review the processes under which Indian tribal governments apply for waivers of statutory and regulatory requirements, and take appropriate steps to streamline those processes.

A. HUD shall, to the extent practicable and permitted by law, consider any application by an Indian tribal government for a waiver of statutory or regulatory requirements, in connection with any program administered by HUD, with a general view toward increasing opportunities for utilizing flexible policy approaches, at the Indian tribal level, in cases in which the proposed waiver is consistent with the applicable Federal policy objectives and is otherwise appropriate.

B. HUD shall, to the extent practicable and permitted by law, render a decision upon a complete application for a waiver within 90 days of receipt of such application by HUD. HUD shall provide the applicant with timely written notice of the decision and, if the application for a waiver is not granted, the reasons for such denial.

C. This section applies only to statutory or regulatory requirements that are discretionary and subject to waiver by HUD. Applicable civil rights statutes and regulations are not subject to waiver.

VIII. Applicability of the Federal Advisory Committee Act

The provisions of the Federal Advisory Committee Act (5 U.S.C. App., Pub. L. 92–463, section 2, Oct. 6, 1972, 86 Stat. 770) (FACA) do not apply to consultations undertaken pursuant to this policy. In accordance with section 204(b) of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, approved March 22, 1995, 109 Stat. 48), FACA is not applicable to consultations between the Federal Government and elected officers of Indian tribal governments (or their designated employees with authority to act on their behalf). As OMB stated in its guidelines implementing section 204(b):

> This exemption applies to meetings between Federal officials and employees and . . . tribal governments, acting through their elected officers, officials, employees, and Washington representatives, at which "views, information or advice" are exchanged concerning the implementation of intergovernmental responsibilities or administration, including those that arise explicitly or implicitly under statute, regulation, or Executive order.
>
> The scope of meetings covered by the exemption should be construed broadly to include any meetings called for any purpose relating to intergovernmental responsibilities or administration. Such meetings include, but are not limited to, meetings called for the purpose of seeking consensus; exchanging views, information, advice, and/or recommendations; or facilitating any other interaction relating to intergovernmental responsibilities or administration. (OMB Memorandum 95–20 (September 21, 1995), pp. 6–7, published at 60 FR 50651, 50653 (September 29, 1995)).

IX. General Provisions

This document has been adopted for the purpose of enhancing government-to-government relationships, communications, and mutual cooperation between the United States Department of Housing and Urban Development and tribes and is not intended to, and does not, create any right to administrative or judicial review, or any other right or benefit or trust responsibility, substantive or procedural, enforceable by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other persons. The provisions of FACA are not applicable to this policy. This document is effective on the date it is signed.

Dated: April 4, 2016.

Julián Castro,

Secretary.

[FR Doc. 2016–14896 Filed 6–22–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5912–N–01]

60-Day Notice of Proposed Information Collection Ginnie Mae Multiclass Securities Program Documents (Forms and Electronic Data Submissions)

AGENCY: Office of the President of Government National Mortgage Association (Ginnie Mae), HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* August 22, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Anna Guido., QDAM, Information Reports Management Officer, Department of Housing and Urban Development, 451 7th Street SW., L'Enfant Plaza Building, Room 4186, Washington, DC 20410; email: *Anna.P.Guido@hud.gov;* telephone (202) 708–2384. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

FOR FURTHER INFORMATION CONTACT: Shalei Choi, Ginnie Mae, 451 7th Street SW., Room B–133, Washington, DC 20410; email—*Shalei.Choi@hud.gov;* telephone—(202) 475–7820; (this is not a toll-free number); the Ginnie Mae Web site at *www.ginniemae.gov* for other available information.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

A. Overview of Information Collection

Title of Proposal: Ginnie Mae Multiclass Securities Program Documents. (Forms and Electronic Data Submissions).

OMB Control Number, if applicable: 2503–0030.

Type of Information Collection: Extension of a currently approved.

Description of the need for the information and proposed use: This information collection is required in connection with the operation of the Ginnie Mae Multiclass Securities program. Ginnie Mae's authority to guarantee multiclass instruments is contained in 306(g)(1) of the National Housing Act ("NHA") (12 U.S.C. 1721(g)(1)), which authorizes Ginnie Mae to guarantee "securities * * * based on or backed by a trust or pool composed of mortgages. * * *" Multiclass securities are backed by Ginnie Mae securities, which are backed by government insured or guaranteed mortgages. Ginnie Mae's authority to operate a Multiclass Securities program is recognized in Section 3004 of the Omnibus Budget Reconciliation Act of 1993 ("OBRA"), which amended 306(g)(3) of the NHA (12 U.S.C. 1271(g)(3)) to provide Ginnie Mae with greater flexibility for the Multiclass Securities program regarding fee structure, contracting, industry consultation, and program implementation. Congress annually sets

Ginnie Mae's commitment authority to guarantee mortgage-backed ("MBS") pursuant to 306(G)(2) of the NHA (12 U.S.C. 1271(g)(2)). Since the multiclass are backed by Ginnie Mae Single Class MBS, Ginnie Mae has already guaranteed the collateral for the multiclass instruments.

The Ginnie Mae Multiclass Securities Program consists of Ginnie Mae Real Estate Mortgage Investment Conduit ("REMIC") securities, Stripped Mortgage-Backed Securities ("SMBS"), and Platinum securities. The Multiclass Securities program provides an important adjunct to Ginnie Mae's secondary mortgage market activities, allowing the private sector to combine and restructure cash flows from Ginnie Mae Single Class MBS into securities that meet unique investor requirements in connection with yield, maturity, and call-option protection. The intent of the Multiclass Securities program is to increase liquidity in the secondary mortgage market and to attract new sources of capital for federally insured or guaranteed loans. Under this program, Ginnie Mae guarantees, with the full faith and credit of the United States, the timely payment of principal and interest on Ginnie Mae REMIC, SMBS and Platinum securities.

Agency form numbers, if applicable: Not applicable.

Members of affected public: For-profit business (mortgage companies, thrifts, savings & loans, etc.).

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:

Type of information collection	(Prepared by)	Number of potential sponsors	Estimated annual frequency per respondant	Total annual responses	Estimated average hourly burden	Estimated annual burden hours
REMIC Securities						
Pricing Letter	Sponsor	18	8	144	0.5	72
Structured Term Sheet	Sponsor	18	8	144	3	432
Trust (REMIC) Agreement	Attorney for Sponsor	18	8	144	1	144
Trust Opinion	Attorney for Sponsor	18	8	144	4	576
MX Trust Agreement	Attorney for Sponsor	18	8	144	0.16	23.04
MX Trust Opinion	Attorney for Sponsor	18	8	144	4	576
RR Certificate	Attorney for Sponsor	18	8	144	0.08	11.52
Sponsor Agreement	Attorney for Sponsor	18	8	144	0.05	7.2
Table of Contents	Attorney for Sponsor	18	8	144	0.33	47.52
Issuance Statement	Attorney for Sponsor	18	8	144	0.5	72
Tax Opinion	Attorney for Sponsor	18	8	144	4	576
Transfer Affidavit	Attorney for Sponsor	18	8	144	0.08	11.52
Supplemental Statement	Attorney for Sponsor	18	0.25	4.5	1	4.5
Final Data Statements (attached to closing letter).	Attorney for Sponsor	18	8	144	32	4608
Accountants' Closing Letter	Accountant	18	8	144	8	1152
Accountants' OSC Letter	Accountant	18	8	144	8	1152
Structuring Data	Accountant	18	8	144	8	1152
Financial Statements	Accountant	18	8	120	1	120
Principal and Interest Factor File Specifications.	Trustee	18	8	144	16	2304
Distribution Dates and Statement	Trustee	18	8	144	0.42	60.48
Term Sheet	Sponsor	18	8	144	2	288
New Issue File Layout	Trustee	18	8	144	4	576
Flow of Funds	Attorney for Trustee	18	8	144	0.16	23.04
Trustee Receipt	Trustee Attorney	18	8	144	2	288
Subtotal				3292.5		14276.82
Platinum Securities						
Deposit Agreement	Depositor	19	10	190	1	190
MBS Schedule	Depositor	19	10	190	0.16	30.4
New Issue File Layout	Depositor	19	10	190	4	760
Principal and Interest Factor File Specifications.	Trustee	19	10	190	16	3040
Subtotal				760		4020.4
Total Annual Responses				4052.5		
Total Burden Hours						18297.22
Calculation of Burden Hours: Sponsors × Frequency per Year = Est. Annual Frequency. Est. Annual Frequency × Est. Average Completion Time = Est. Annual Burden Hours.						

B. Solicitation of Public Comment

This Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35 as amended.

Dated: June 17, 2016.

Gregory Keith,

Acting Executive Vice President, Government National Mortgage Association.

[FR Doc. 2016–14926 Filed 6–22–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5955–N–01]

Paperwork Reduction Act—Rental Assistance Demonstration (RAD) Documents

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The Rental Assistance Demonstration allows Public Housing, Moderate Rehabilitation (Mod Rehab), Rent Supplement (Rent Supp), and Rental Assistance Payment (RAP) properties to convert to long-term project-based Section 8 rental assistance contracts. The documents that subject to this notice are those used to process and complete the conversion process for Public Housing, Mod Rehab, Rent Supp, and RAP properties.

On March 17, 2016, HUD published a 60-day notice announcing proposed changes to the existing Rental Assistance Demonstration (RAD) Documents and solicited public comments on the proposal.

An emergency request has been made to the Office of Management and Budget (OMB) for a short term six-month extension of the existing RAD Documents so that the program can continue to operate while HUD reviews and responds to the comments received during the 60-day comment period, and completes the Paperwork Reduction Act submission process for amending and renewing the RAD Documents for a period of three years.

DATES: Office of Management and Budget approval of the existing RAD Documents is set to expire on June 30, 2016.

FOR FURTHER INFORMATION CONTACT: Stacy Harrison, Recapitalization Program Specialist, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410–8000; telephone: 202–402–4234 (this is not a toll-free number). Hearing- or speech-impaired individuals may access these numbers through TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

Dated: June 17, 2016.

Genger Charles,

General Deputy Assistant Secretary For Housing.

[FR Doc. 2016–14924 Filed 6–22–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5951–N–01]

Notice of Proposal To Establish a Tribal Intergovernmental Advisory Committee; Request for Comments on Committee Structure

AGENCY: Office of Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: This notice solicits comments and recommendations regarding the establishment of a Tribal Intergovernmental Advisory Committee (TIAC), consisting of tribal representatives, to assist HUD further develop and maintain its Indian housing programs. The TIAC is intended to further communications between HUD and Federally recognized Indian tribes on HUD programs, make recommendations to HUD regarding current program regulations, provide advice in the development of HUD's American Indian and Alaska Native housing priorities, and encourage peer learning and capacity building among tribes and non-tribal entities. Consistent with HUD's Tribal Government-to-Government Consultation Policy, published elsewhere in this **Federal Register**, this notice solicits input on the structure of the TIAC.

DATES: Comments on the proposed structure of the TIAC are due on or before: June 23, 2016.

ADDRESSES: Interested persons are invited to submit comments on the structure of the Tribal Intergovernmental Advisory Committee. There are two methods for comments to be included in the docket for this rule. Additionally, all submissions must refer to the above docket number and title.

1. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of the General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Room 10276, Washington, DC 20410–0500.

2. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages the electronic submission of comments. Electronic submission allows the maximum time to prepare and submit a nomination, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by interested members of the public. Individuals should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule. *No Facsimile Comments.* Facsimile (FAX) comments are not acceptable.

Public Inspection of Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the submissions must be scheduled by calling the Regulations Division at (202) 708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Information Relay Service at (800) 877–8339. Copies of all submissions are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Heidi J. Frechette, Deputy Assistant Secretary for Native American Programs, Office of Public and Indian

Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 4126, Washington, DC 20410–5000, telephone, (202) 402–7598 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the toll-free Federal Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this **Federal Register**, HUD is publishing its updated Tribal Government-to-Government Consultation Policy. Consistent with Executive Order 13175, HUD's Tribal Government-to-Government Consultation Policy recognizes the right of Indian tribes to self-government, and supports tribal sovereignty and self-determination. It provides that HUD will engage in regular and meaningful consultation and collaboration with Indian tribal officials in the development of federal policies that have tribal implications. Executive Orders 13175 and 13647 also require Federal agencies to advance tribal self-governance and ensure that the rights of sovereign tribal governments are fully respected by conducting open and candid consultations.

To further enhance consultation and collaboration with tribal governments, HUD is proposing to establish the TIAC. Several Federal agencies have established similar tribal advisory committees, including the Environmental Protection Agency, the Department of Health and Human Services, and the Department of the Treasury. These advisory committees convene periodically during the year to exchange information with agency staff, notify tribal leaders of activities or policies that could affect tribes, and provide guidance on consultation. Prior to HUD's establishment of the TIAC, this notice solicits input into the structure of the committee.

II. Proposed Structure of the TIAC

A. *Purpose and Role of the TIAC.* The purposes of the TIAC are:

(1) To further facilitate intergovernmental communication between HUD and Federally recognized Indian tribal leaders on all HUD programs;

(2) To make recommendations to HUD regarding current program regulations that may require revision, as well as suggest rulemaking methods to develop such changes;

(3) To advise in the development of HUD's American Indian and Alaska Native (AIAN) housing priorities; and

(4) To encourage peer learning and capacity building among tribes and non-tribal entities. The role of the TIAC is to provide recommendations and input to HUD and to provide a vehicle for regular and meaningful consultation and collaboration with tribal officials. HUD will maintain the responsibility to exercise program management, including the drafting of HUD notices and guidance.

B. *Charter and Protocols.* The TIAC will develop its own ruling charter and protocols. HUD will provide staff for the TIAC to act as a liaison between TIAC and HUD officials, manage meeting logistics, and provide general support for TIAC activities.

C. *Meetings and Participation.* Subject to availability of federal funding, the TIAC will meet in-person at least twice a year, to exchange information with HUD staff, discuss agency policies and activities that could affect tribes, and facilitate further consultation with tribal leaders. HUD will pay for these meetings, including the member's cost to travel to these meetings. The TIAC may meet on a more frequent basis by conference calls or other forms of communication. Additional in-person meetings may be scheduled at HUD's discretion. Participation at TIAC meetings will be limited to TIAC members or their alternates. Alternates must be designated in writing by the member's tribal government to act on their behalf. TIAC committee members may bring one additional staff person to the meeting at their expense. Meeting minutes will be available on the HUD Web site.

D. *TIAC Membership.* The TIAC will be comprised of HUD representatives and tribal delegates from across the country. The TIAC will be composed of up to four HUD officials and up to eight tribal representatives. One tribal member will represent each of the six HUD ONAP regions. The two remaining tribal members will serve at-large. Only duly elected or appointed tribal leaders may serve as tribal members or alternates of the TIAC. One of the tribal members will be selected by the committee to serve as the chairperson.

The Secretary shall appoint the members of the TIAC. TIAC tribal delegates will serve a term of 2 years. To ensure consistency between tribal terms, delegates will have a staggered term of appointment. In order to establish a staggered term of appointment, half of the tribal members appointed in the inaugural year of the TIAC will serve 2 years and the other half will serve 3 years. Delegates must designate their preference to serve 2 or 3 years; however, HUD will make the final determination on which members will serve for 3 years. Once these members complete these initial terms, future tribal members will serve terms that last 2 years.

E. The establishment of the TIAC is intended to enhance government-to-government relationships, communications, and mutual cooperation between HUD and tribes and is not intended to, and will not, create any right to administrative or judicial review, or any other right or benefit or trust responsibility, substantive or procedural, enforceable by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other persons.

III. Request for Nominations

Once a general structure for the TIAC is established, HUD intends to publish a request for nominations for the TIAC in the **Federal Register** and will appoint the members of the TIAC from the pool of nominees it receives under this request. HUD will announce its final selections for TIAC membership in a subsequent **Federal Register** notice. Members will be selected based on proven experience and engagement in AIAN housing and community development matters. At-large members will be selected based on their ability to represent specific interests that might not be represented by the selected regional members.

Dated: June 20, 2016.

Lourdes Castro Ramirez,

Principal Deputy Assistant Secretary for Public and Indian Housing.

[FR Doc. 2016–14895 Filed 6–22–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2014–0018; 96300–1671–0000–R4]

Conference of the Parties to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES); Seventeenth Regular Meeting; Provisional Agenda; Announcement of Public Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: The United States, as a Party to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), will attend the seventeenth regular meeting of the Conference of the Parties to CITES

(CoP17) in Johannesburg, South Africa, September 24 to October 5, 2016. Currently, the United States is developing its negotiating positions on proposed resolutions, decisions, and amendments to the CITES Appendices (species proposals), as well as other agenda items that have been submitted by other Parties, the permanent CITES committees, and the CITES Secretariat for consideration at CoP17. With this notice we announce the provisional agenda for CoP17, solicit your comments on the items on the provisional agenda, and announce a public meeting to discuss the items on the provisional agenda.

DATES:

Public meeting: The public meeting will be held on July 19, 2016, at 1:00 p.m.

Comment submission: In developing the U.S. negotiating positions on species proposals and proposed resolutions, decisions, and other agenda items submitted by other Parties, the permanent CITES committees, and the CITES Secretariat for consideration at CoP17, we will consider written information and comments you submit if we receive them by August 8, 2016.

ADDRESSES:

Public Meeting

The public meeting will be held in the South Interior Building Auditorium at 1951 Constitution Avenue NW., Washington, DC. Directions to the building can be obtained by contacting the Division of Management Authority (see **FOR FURTHER INFORMATION CONTACT**). For more information about the meeting, see "Announcement of Public Meeting" under **SUPPLEMENTARY INFORMATION**.

Comment Submission

You may submit comments pertaining to items on the provisional agenda for discussion at CoP17 by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–HQ–IA–2014–0018 (the docket number for this notice).
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: FWS–HQ–IA–2014–0018; Division of Policy, Performance, and Management Programs; U.S. Fish and Wildlife Service; 5275 Leesburg Pike, MS BPHC; Falls Church, VA 22041.

We will not consider comments sent by email or fax or to an address not listed in **ADDRESSES**. If you submit a comment via *http://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the Web site. If you submit a hardcopy comment that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy comments on *http://www.regulations.gov.* Comments and materials we receive, as well as supporting documentation, will be available for public inspection on *http://www.regulations.gov,* or by appointment, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays, at: U.S. Fish and Wildlife Service Headquarters, Division of Management Authority, 5275 Leesburg Pike, Falls Church, VA 22041–3803; telephone 703–358–2095.

FOR FURTHER INFORMATION CONTACT: For information pertaining to resolutions, decisions, and other agenda items, contact: Craig Hoover, Chief, Division of Management Authority; telephone 703–358–2095; facsimile 703–358–2298. For information pertaining to species proposals, contact: Rosemarie Gnam, Chief, Division of Scientific Authority; telephone 703–358–1708; fascsimile 703–358–2276.

SUPPLEMENTARY INFORMATION:

Background

The Convention on International Trade in Endangered Species of Wild Fauna and Flora, hereinafter referred to as CITES or the Convention, is an international treaty designed to control and regulate international trade in certain animal and plant species that are now or potentially may become threatened with extinction. These species are listed in Appendices to CITES, which are available on the CITES Secretariat's Web site at *http://www.cites.org/eng/app/index.php.*

Currently 181 countries and the European Union have ratified, accepted, approved, or acceded to CITES; these 182 entities are known as Parties. The Convention calls for regular biennial meetings of the Conference of the Parties, unless the Conference of the Parties decides otherwise. At these meetings, the Parties review the implementation of CITES, make provisions enabling the CITES Secretariat in Switzerland to carry out its functions, consider amendments to the lists of species in Appendices I and II, consider reports presented by the Secretariat and the permanent CITES committees (Standing, Animals, and Plants Committees), and make recommendations for the improved effectiveness of CITES. Any country that is a Party to CITES may propose amendments to Appendices I and II, resolutions, decisions, and other agenda items for consideration by all of the Parties at the meetings.

This is our fifth in a series of **Federal Register** notices that, together with the announced public meeting, provide you with an opportunity to participate in the development of U.S. negotiating positions for the seventeenth regular meeting of the Conference of the Parties to CITES (CoP17). We published our first CoP17-related **Federal Register** notice on June 27, 2014 (79 FR 36550), in which we requested information and recommendations on species proposals for the United States to consider submitting for consideration at CoP17. In that notice, we also described the U.S. approach to preparations for CoP17. We published our second such **Federal Register** notice on May 11, 2015 (80 FR 26948), in which we requested information and recommendations on proposed resolutions, decisions, and other agenda items for the United States to consider submitting for consideration at CoP17, and provided preliminary information on how to request approved observer status for non-governmental organizations that wish to attend the meeting. In our third CoP17-related **Federal Register** notice, published on August 26, 2015 (80 FR 51830), we requested public comments and information on species proposals that the United States is considering submitting for consideration at CoP17; and in our fourth such notice, published on December 4, 2015 (80 FR 75873), we requested public comments and information on proposed resolutions, decisions, and other agenda items that the United States was considering submitting for consideration at CoP17, and provided more information on how to request approved observer status for non-governmental organizations that wish to attend the meeting. A link to the complete list of those **Federal Register** notices, along with information on U.S. preparations for CoP17, can be found at *http://www.fws.gov/international/cites/cop17.* You may obtain additional information on those **Federal Register** notices from the following sources: For information on proposed resolutions, decisions, and other agenda items, contact the U.S. Fish and Wildlife Service, Division of Management Authority, 5275 Leesburg Pike, MS–IA, Falls Church, VA 22041; and for information on species proposals, contact the Division of Scientific Authority, 5275 Leesburg Pike, MS–IA, Falls Church, VA 22041. Our regulations governing this public process are found in 50 CFR 23.87.

On April 26 and 27, 2016, the United States submitted to the CITES Secretariat, for consideration at CoP17, its species proposals, proposed resolutions, proposed decisions, and other agenda items. These documents are available on our Web site at *http://www.fws.gov/international/cites/cop17.*

Announcement of Provisional Agenda for CoP17

The provisional agenda for CoP17 is currently available on the CITES Secretariat's Web site at *http://www.cites.org/eng/cop/17/doc/index.php.* The working documents associated with the items on the provisional agenda, including proposed resolutions, proposed decisions, and discussion documents, are also available on the Secretariat's Web site. To view the working document associated with a particular agenda item, access the provisional agenda at the above Web site, locate the particular agenda item, and click on the document link for that agenda item in the column entitled "Document." Finally, the species proposals that will be considered at CoP17 are available on the Secretariat's Web site. Proposals for amendment of Appendices I and II can be accessed at the web address given above. We look forward to receiving your comments on the items on the provisional agenda.

Announcement of Public Meeting

We will hold a public meeting to discuss the items on the provisional agenda for CoP17. The public meeting will be held on the date specified in the **DATES** section and at the address specified in the **ADDRESSES** section. You can obtain directions to the building by contacting the Division of Management Authority (see the **FOR FURTHER INFORMATION CONTACT** section above). Please note that the South Interior Building Auditorium is accessible to the handicapped and all persons planning to attend the meeting will be required to present photo identification when entering the building. Persons who plan to attend the meeting and who require interpretation for the hearing impaired must notify the Division of Management Authority by July 5, 2016. For those who cannot attend the public meeting but are interested in watching via live stream please go to our Web site *http://www.fws.gov/international/cites/cop17/index.html,* and look for the link to the live feed.

Future Actions

Through an additional notice and Web site posting in advance of CoP17, we will inform you about tentative U.S. negotiating positions on species proposals, proposed resolutions, proposed decisions, and agenda items that were submitted by other Parties, the permanent CITES committees, and the CITES Secretariat for consideration at CoP17.

Authority: The primary author of this notice is Clifton A. Horton, Division of Management Authority; under the authority of the U.S. Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: June 9, 2016.

Stephen Guertin,

Acting Director, Fish and Wildlife Service.

[FR Doc. 2016–14870 Filed 6–22–16; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R7–ES–2016–N092; FF07CAMM00–FX–FXFR133707REG04]

Marine Mammals; Incidental Take During Specified Activities; Proposed Incidental Harassment Authorization for Pacific Walruses in Alaska and Associated Federal Waters

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of application and proposed incidental harassment authorization; availability of draft environmental assessment; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), in response to a request under the Marine Mammal Protection Act of 1972 (MMPA), as amended, from Quintillion Subsea Operation, LLC, propose to authorize the incidental taking by harassment of small numbers of Pacific walruses from July 15–November 15, 2016. The area specified for inclusion in the proposed authorization includes Federal waters of the northern Bering, Chukchi, and Southern Beaufort Seas, the marine waters of the State of Alaska, and coastal land adjacent to Nome, Kotzebue, Point Hope, Wainwright, Barrow, and Oliktok Point, as shown in Figure 1. The applicant has requested this authorization for its planned cable-laying activities. We anticipate no take by injury or death and include none in this proposed authorization, which if finalized, will be for take by harassment only.

DATES: We will consider comments we receive on or before July 25, 2016.

ADDRESSES:

Document availability: The incidental harassment authorization request, associated draft environmental assessment, and literature cited, are available for viewing at *http://www.fws.gov/alaska/fisheries/mmm/iha.htm.*

Comments submission: You may submit comments on the proposed incidental harassment authorization and associated draft environmental assessment by one of the following methods:

- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: Kimberly Klein, U.S. Fish and Wildlife Service, MS 341, 1011 East Tudor Road, Anchorage, AK 99503;
- *Fax:* 907–786–3816, Attn: Kimberly Klein; or
- *Email comments to: FW7_AK_Marine_Mammals@fws.gov.*

Please indicate whether your comments apply to the proposed incidental harassment authorization or the draft environmental assessment. We will post all hardcopy comments on *http://www.fws.gov/alaska/fisheries/mmm/iha.htm.* See Request for Public Comments below for more information.

FOR FURTHER INFORMATION CONTACT: Copies of the application, the list of references used in the notice, and other supporting materials may be downloaded from the Web at: *http://www.fws.gov/alaska/fisheries/mmm/iha.htm.* You may also contact Kimberly Klein, by mail at Marine Mammals Management, U.S. Fish and Wildlife Service, MS 341, 1011 East Tudor Road, Anchorage, AK 99503; by email at *kimberly_klein@fws.gov;* or by telephone at 1–800–362–5148, to request documents.

SUPPLEMENTARY INFORMATION: In response to a request from Quintillion Subsea Operation, LLC (Quintillion or "the applicant"), we propose to authorize the incidental taking by harassment of small numbers of Pacific walruses from July 15–November 15, 2016, under section 101(a)(5)(D) of the Marine Mammal Protection Act of 1972 (MMPA), as amended. Quintillion has requested this authorization for its planned cable-laying activities in Federal waters of the northern Bering, Chukchi, and southwestern Beaufort Seas, the marine waters of the State of Alaska, and coastal land adjacent to Nome, Kotzebue, Point Hope, Wainwright, Barrow, and Oliktok Point, as specified in Figure 1. We anticipate no take by injury or death and include none in this proposed authorization, which, if finalized, would be for take by harassment only.

Executive Summary

Why We Need To Publish a Draft Incidental Harassment Authorization (IHA)

Section 101(a)(5)(D) of the MMPA (16 U.S.C. 1361 *et seq.*) directs the Service to allow, upon request, and for periods of not more than 1 year, the incidental, but not intentional take of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical area if certain findings are made regarding the effects of the take. The Service was petitioned by Quintillion on October 29, 2015, to provide authorization for the incidental take by harassment of Pacific walruses (*Odobenus rosmarus divergens*) and polar bears (*Ursus maritimus*) for a cable-laying project, which is intended to improve broadband internet service in northern Alaska. After receiving comments on the initial application, Quintillion made revisions and submitted an updated IHA application on February 3, 2016. Quintillion subsequently withdrew its application for incidental take of polar bears on April 25, 2016, citing several factors, including changes to the project that reduce the already-low probability of encounters with polar bears. This document announces and explains the Service's proposed authorization of incidental take of small numbers of Pacific walruses from Quintillion's cable-laying project in the State of Alaska and associated Federal waters from July 15–November 15, 2016.

The Effect of This Authorization

The MMPA allows the Service to authorize, upon request, the incidental take of small numbers of marine mammals as part of a specified activity within a specified geographic region. In this case, the Service may authorize the incidental, but not intentional, take by harassment of small numbers of Pacific walruses by Quintillion during the specified cable-laying project activities if we find that such harassment during each period will:

- Have no more than a "negligible impact" on the species or stock of Pacific walrus; and
- Not have an "unmitigable adverse impact" on the availability of the species or stock for taking for subsistence uses.

The Service may stipulate the permissible methods of taking and require mitigation, monitoring, and reporting of such takings, which are meant to reduce or minimize negative impacts to the Pacific walrus.

Request for Public Comments

We intend that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, we request comments or suggestions on this proposed authorization. We particularly seek comments concerning:

- Whether the proposed authorization, including the proposed activities, will have a negligible impact on the species or stock of Pacific walrus.
- Whether the proposed authorization will ensure that an unmitigable adverse impact on the availability of Pacific walruses for subsistence taking does not occur.
- Whether there are any additional provisions we may wish to consider for ensuring the conservation of the Pacific walrus.

You may submit your comments and materials concerning this proposed authorization by one of the methods listed in **ADDRESSES**.

If you submit a comment via *FW7_AK_Marine_Mammals@fws.gov,* your entire comment—including any personal identifying information—may be available to the public. If you submit a hardcopy comment that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy comments on *http://www.fws.gov/alaska/fisheries/mmm/iha.htm.*

Background

Section 101(a)(5)(D) of the MMPA, as amended (16 U.S.C. 1371(a)(5)(D)), authorizes the Secretary of the Interior (the Secretary) to allow, upon request of a citizen and subject to such conditions as the Secretary may specify, the incidental but not intentional taking by harassment of small numbers of marine mammals of a species or population stock by such citizens who are engaging in a specified activity within a specified region. Incidental taking may be authorized only if the Secretary finds that such take during each period concerned will have a negligible impact on such species or stock, and will not have an unmitigable adverse impact on the availability of such species or stock for subsistence use.

Section 101(a)(5)(D) of the MMPA establishes a process by which citizens of the United States can apply for an authorization for incidental take of small numbers of marine mammals where the take will be limited to harassment during a period of not more than 1 year. We refer to these incidental harassment authorizations as "IHAs."

The term "take," as defined by the MMPA, means to harass, hunt, capture, or kill, or to attempt to harass, hunt, capture, or kill any marine mammal. Harassment, as defined by the MMPA, means any act of pursuit, torment, or annoyance which: (i) Has the potential to injure a marine mammal or marine mammal stock in the wild (the MMPA calls this "Level A harassment"), or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (the MMPA calls this "Level B harassment").

The terms "small numbers," "negligible impact," and "unmitigable adverse impact" are defined in 50 CFR 18.27, the Service's regulations governing take of small numbers of marine mammals incidental to specified activities. "Small numbers" is defined as a portion of a marine mammal species or stock whose taking would have a negligible impact on that species or stock. However, we do not rely on that definition here, as it conflates the terms "small numbers" and "negligible impact," which we recognize as two separate and distinct requirements. Instead, in our small numbers determination, we evaluate whether the number of marine mammals likely to be taken is small relative to the size of the overall population. "Negligible impact" is defined as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to adversely affect the species or stock through effects on annual rates of recruitment or survival. "Unmitigable adverse impact" is defined as an impact resulting from the specified activity (1) that is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by (i) causing the marine mammals to abandon or avoid hunting areas, (ii) directly displacing subsistence users, or (iii) placing physical barriers between the marine mammals and the subsistence hunters; and (2) that cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

In order to issue an IHA, the Service must set forth the following: (1) Permissible methods of taking; (2) means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance; and (3) requirements pertaining to the monitoring and reporting of such takings. Habitat areas of significance for

Pacific walruses in the project area include (a) marginal sea-ice zones, (b) areas with consistent polynyas in consolidated pack ice or multiyear ice, (c) areas of high benthic productivity, (d) areas where nutrient-rich ocean currents converge, and (e) terrestrial haulouts. The proposed activities will not be conducted in the vicinity of sea ice, eliminating potential impacts to the first two habitat types. Areas of high benthic productivity and convergence of nutrient-rich currents are important because they generate important feeding areas. The Service, therefore, must specify avoidance and minimization measures for effecting the least practicable impact of the proposed action on important feeding areas and terrestrial haulouts.

Summary of Request

On October 29, 2015, Quintillion submitted a request to the Service for the nonlethal taking by harassment of Pacific walruses and polar bears that may occur incidental to a cable-laying project. Quintillion is proposing to install 1,904 kilometers (km) (1,183 miles (mi)) of submerged fiber optic cable on the seafloor of the Bering, Chukchi, and Beaufort Seas off the northern and western coasts of Alaska during the open-water season of 2016. The Quintillion cable project or "the proposed action" consists of a main trunk line and six branching lines with links to the existing terrestrial networks of six rural Alaskan communities. An amendment with updated information was received in February 2016, and Quintillion withdrew its request for incidental take of polar bears on April 25, 2016. A complete copy of Quintillion's request and supporting documents may be obtained as specified above in **ADDRESSES**.

The project is most likely to encounter Pacific walruses in the Chukchi Sea in August and September. The cable-laying activities are proposed for the northern Bering Sea after mid-July when most animals have moved either northward into the Chukchi Sea or southward to Bristol Bay, where no cable-laying activities are proposed. The Southern Beaufort Sea is outside of the normal range of the species and is, therefore, considered "extralimital" to the normal range of the species, and encounters are unlikely. When Pacific walruses are encountered, they may react to the presence of Quintillion's vessels or the sounds of the cable-laying activities. Thrusters, echo sounders, and beacon transceivers that will be used by the cable-laying ships during this project may generate noise levels capable of causing acoustic harassment to Pacific walruses in the local area.

Quintillion is requesting incidental take by Level B harassment of Pacific walruses from disruption of behavioral patterns and exposure to sound levels exceeding 160 decibels (dB; all dB levels given herein are re: 1 μPa). The number of actual takes from sound exposure will depend upon the number of individuals occurring within the 160-dB ensonification zone. The "ensonification zone" is the area surrounding a sound source where received sound levels may exceed the specified threshold. Quintillion is not requesting authorization for take by Level A harassment. Quintillion does not believe that Level A take will occur because the project is not expected to generate noise levels at or above the level considered by the Service to have the potential to cause injury. Quintillion estimates that the project will generate sound levels no greater than 180 $\mathrm{dB_{rms}}$ ($\mathrm{dB_{rms}}$ refers to the root-mean-squared dB level, the square root of the average of the squared sound pressure level over some duration—typically 1 second). Pursuant to conclusions reached by the National Oceanic and Atmospheric Administration (NOAA), the Service considers sound levels above 190 $\mathrm{dB_{rms}}$ to have the potential to cause injury to Pacific walruses and result in take due to Level A harassment (*e.g.*, NMFS 1998; HESS 1999).

Prior to issuing an IHA in response to this request, the Service must evaluate the level of activities described in the application, the associated potential impacts to Pacific walruses, and the potential effects on the availability of the species for subsistence use. The Service is tasked with analyzing the impact that the proposed lawful activities will have on Pacific walruses during normal operating procedures.

Description of the Specified Activities and Geographic Area

The planned Quintillion cable project will occur in the marine waters of the northern Bering, Chukchi, and southwestern Beaufort Seas, in waters of the State of Alaska, and on coastal land of Alaska (Figure 1). The main trunk line is 1,317 km (818 mi) in length. The branching lines range between 27 km (17 mi) and 233 km (145 mi) in length and extend between the trunk line and the coastal communities of Nome, Kotzebue, Point Hope, Wainwright, and Barrow. Another branching line will extend to Oliktok Point, located 260 km (162 mi) southeast of Barrow. This line will connect over land with the community of Nuiqsut and the Prudhoe Bay industrial center. Additional project details are available in Quintillion's IHA application, available online at *http://www.fws.gov/alaska/fisheries/mmm/iha.htm.*

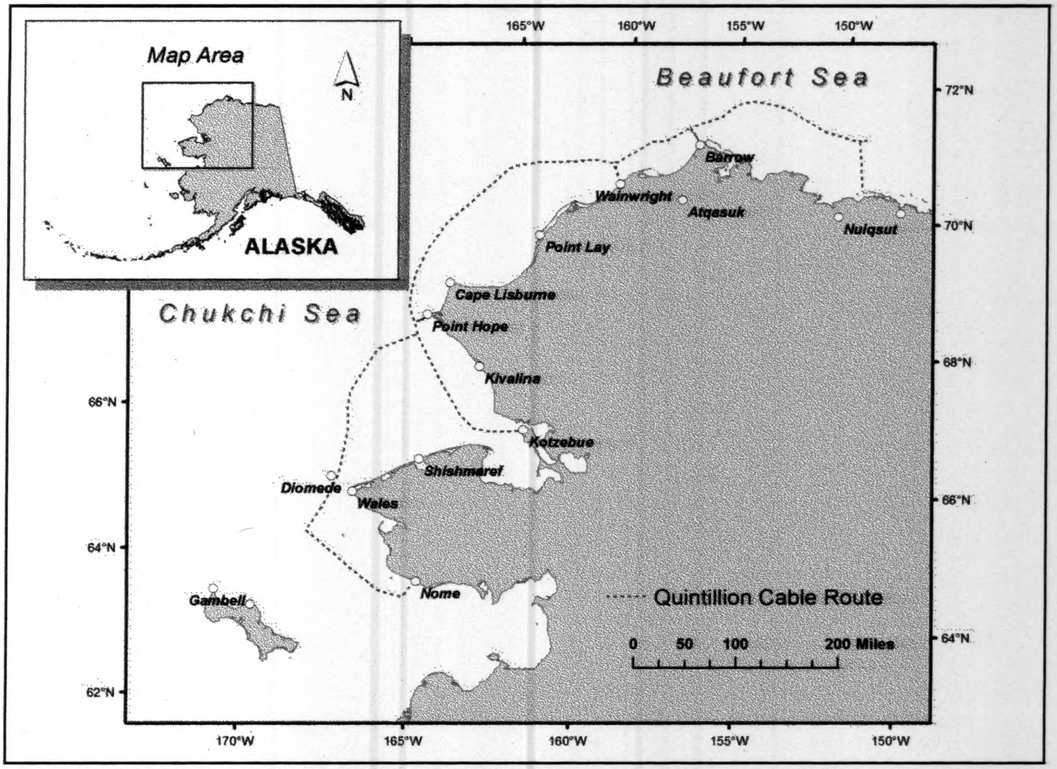

Figure 1. Quintillion Subsea Operations, LLC's proposed fiber optic cable network.

All activities associated with the IHA request, including mobilization, preliminary work, cable laying, post-burial work, and demobilization of survey and support crews are planned to occur June 1–October 31, 2016. Operations in the Bering Sea will begin near Nome in mid-June and follow the receding sea ice northward into the northern Bering Sea. Work in the Bering Sea between Nome and the Bering Strait is proposed to occur from mid-July to mid-August 2016. Work in the open waters of the Chukchi Sea north of the Bering Strait and in the Beaufort Sea will be done in August and September. Nearshore cable landing work near Oliktok Point, Barrow, Wainwright, and Point Hope will begin in July and will continue in August–October while work is also being conducted offshore. Work may be conducted day or night. The operations will take approximately 150 days within the work window.

Before cable is laid, a pre-lay grapnel run will be completed along the proposed cable route where burial is required. A grapnel is a small anchor with three or more flukes, used for grappling or dragging. The objective of the operation is the identification and clearance of any seabed debris. The grapnel run will employ towed grapnels and will be conducted by a tugboat. Any debris recovered during these operations will be discharged ashore and disposed of in accordance with applicable regulations. If any debris cannot be recovered, then a local reroute will be planned to avoid the debris.

The cable-laying operations will be conducted from the Cable Ship (C/S) *Ile de Brehat* and/or its sister ships (*Ile de Sein, Ile de Batz*). The three ships may operate simultaneously in different locations. All three ships are 140 meters (m) or 460 feet (ft) in length and 23 m (77 ft) in breadth, with berths for a crew of 70. Each ship is propelled by two 4,000-kilowatt (kW) fixed-pitch propellers. Dynamic positioning is maintained by two 1,500-kW bow thrusters, two 1,500-kW aft thrusters, and one 1,500-kW fore thruster. Sound source measurements have not been conducted specific to the C/S *Ile de Brehat,* but acoustic studies for similar vessels have shown thruster noise measurements of 171–180 dB_{rms} at 1 m (Nedwell *et al.* 2003; Samsung 2009; Deepwater Wind 2012).

Support vessels include a tug and barge that will be primarily used for nearshore operations on the branch lines. Submerged cable components will include the cable, interconnecting hardware, and repeaters. The cable will be placed on the seafloor surface or will be buried. Burial method will depend on bottom substrate, water depth, and location. Echo sounders, transceivers, and transponders will be used to monitor the water depth and the position of equipment on the seafloor.

Where cable is to be laid on the seafloor surface, the cable ships will install the cable as close as possible to the planned route with the correct amount of cable slack to enable the cable to conform to the contours of the seabed without loops or suspensions. A slack plan will be developed that uses direct bathymetric data and a catenary modeling system to control the ship and the cable payout speeds to ensure the cable is accurately placed. A dive team and the tug and barge will lay cable in nearshore waters too shallow for the C/S *Ile de Brehat.*

Burial methods will depend on water depth. In depths greater than 12 m (39.4 ft), the cable will be buried using a burial plough pulled by the cable ship. The plough is pulled by a tow wire as cable is fed through a depressor that pushes it into a trench. Burial depth is controlled by adjusting the front skids. The normal tow speed is approximately 600 meters per hour (m/hr) (0.37 miles per hour (mph) or 0.32 knots (kn)). During cable laying, the cable ship will not be able to alter course or speed to avoid marine mammals, but the slow speed and constant sound production will provide ample warning, allowing Pacific walruses to retreat before they are close enough to be harmed.

In water depths less than 12 m (39.4 ft), burial will be by a tug-pulled jet sled, tracked Remotely Operated Vehicle (ROV), or by a dive team using hand-jetting equipment, subject to seabed conditions in the area. Burial depths will generally be 2–3 m (6.6–9.8 ft). Nearer to shore, where seasonal ice scouring occurs, the cable will be floated on the surface and then pulled through an existing horizontal directionally drilled bore pipe to the beach manhole where it will be spliced to the terrestrial cable. The floated cable portion will then be lowered to the seabed by divers and buried (using a burial method as described above) from the bore pipe seaward.

While it is expected that the cable trenches will fill in by natural current processes, it is important to ensure that cable splices and interconnections are fully buried, and that there are no plough skips at locations where burial is critical. To ensure proper burial at critical locations, the ROV will be used to conduct post-lay inspection and burial along an estimated 10 km (6.2 mi) of the burial route.

Description of Marine Mammals in the Area of Specified Activity

The stock of Pacific walruses is composed of a single panmictic population inhabiting the shallow continental shelf waters of the Bering and Chukchi Seas (Lingqvist *et al.* 2009; Berta and Churchill 2012). The size of the stock has never been known with certainty. In 2006, the United States and Russia conducted a joint aerial survey in the pack ice of the Bering Sea using thermal imaging systems and satellite transmitters to count Pacific walruses in the water and hauled out on sea ice. The number within the surveyed area was estimated at 129,000 with 95 percent confidence limits of 55,000 to 507,000 individuals. This estimate is considered a minimum: Weather conditions forced termination of the survey before large areas were surveyed (Speckman *et al.* 2011).

Distribution is largely influenced by the extent of the seasonal pack ice and prey densities. From April to June, most of the population migrates from the Bering Sea through the Bering Strait and into the Chukchi Sea. Pacific walruses tend to migrate into the Chukchi Sea along lead systems that develop in the sea ice. During the open-water season, Pacific walruses are closely associated with the edge of the seasonal pack ice from Russian waters to areas west of Point Barrow, Alaska. Most of these animals remain in the Chukchi Sea throughout the summer months, but a few occasionally range into the Beaufort Sea. Oil and gas industry observers reported 35 sightings east of Point Barrow (~156.5° W.) between 1995 and 2012 (Kalxdorff and Bridges 2003; AES Alaska 2015; USFWS unpublished data).

The pack ice usually advances rapidly southward in late fall, and most Pacific walruses return to the Bering Sea by mid- to late-November. During the winter breeding season, three concentration areas form in the Bering Sea where open leads, polynyas, or thin ice occur (Fay *et al.* 1984; Garlich-Miller *et al.* 2011). While the specific location of these groups varies annually depending upon the sea-ice extent, one group generally occurs near the Gulf of Anadyr, another south of St. Lawrence Island, and a third in the southeastern Bering Sea south of Nunivak Island.

Pacific walruses are usually found in waters of 100 m (328 ft) or less although they are capable of diving to greater depths. They use sea ice as a resting platform over feeding areas, as well as for giving birth, nursing, passive transportation, and avoiding predators (Fay 1982; Ray *et al.* 2006). Native hunters have reported incidences of Pacific walruses preying on seals; other items such as fish and birds are occasionally taken (Sheffield and Grebmeier 2009; Seymour *et al.* 2014), but benthic invertebrates are the primary food source. Foraging trips may last for several days, during which the animals dive to the bottom nearly continuously. Most foraging dives last 5–10 minutes, with surface intervals of 1–2 minutes. The disturbance of the sea floor by foraging Pacific walruses releases nutrients into the water column, provides food for scavenger organisms, contributes to the diversity of the benthic community, and is thought to have a significant influence on the ecology of the Bering and Chukchi Seas (Ray *et al.* 2006).

Bivalve clams of the genera *Macoma, Serripes,* and *Mya* appear to be the most important prey based on both stomach contents and prey availability at Pacific walrus feeding areas (Sheffield and Grebmeier 2009). Feder *et al.* (1989) found summer and fall feeding areas in the Chukchi Sea to be dominated by muddy substrates supporting high biomasses of *Macoma calcarea.* Hanna Shoal is the most important foraging area for Pacific walruses (Brueggeman *et al.* 1990, 1991; MacCracken 2012; Jay *et al.* 2012). Jay *et al.* (2012) tracked radio-tagged individuals to estimate areas of foraging and occupancy in the Chukchi Sea during June–November of 2008–2011 (years when sea ice was sparse over the continental shelf) and observed high use areas in the relatively shallow waters of Hanna Shoal. The unique bathymetric and current patterns at Hanna Shoal deposit nutrients from the Bering Sea on the ocean floor where they feed a rich benthic ecosystem. Based on this information, the Service designated 24,600 km² (9,500 mi²) of the Chukchi Sea as the Hanna Shoal Walrus Use Area (HSWUA).

Pacific walruses are social and gregarious animals. They travel and haul out onto ice or land in groups, and spend approximately 20–30 percent of their time out of the water. Hauled-out animals tend to be in close physical contact. Young animals often lie on top of adults. The size of the hauled-out groups can range from a few animals up to several thousand individuals. The largest aggregations occur at land haulouts.

Use of terrestrial haulouts in the eastern Chukchi Sea by large numbers has been common during recent years of low summer sea ice, when the edge of the pack ice has moved north into the deep Arctic Basin where Pacific walruses cannot feed (due to too great a water depth). In recent years, the barrier islands north of Point Lay, Alaska, have held large aggregations of up to 20,000–40,000 animals in late summer and fall (Monson *et al.* 2013). Pacific walruses hauled out near Point Lay have travelled to Hanna Shoal during feeding bouts.

Polar bears are known to prey on Pacific walruses, particularly calves; killer whales (*Orcinus orca*) have been known to take all age classes (Frost *et al.* 1992; Melnikov and Zagrebin 2005). Predation rates are unknown but are thought to be highest near terrestrial haulout sites where large aggregations can be found. Few observations exist of predation upon Pacific walruses farther offshore.

Pacific walruses have been hunted for food and other purposes by coastal-dwelling Alaska Natives and Native peoples of Chukotka, Russian Federation for thousands of years. Combined harvest mortality from 2000–2014 for the United States and Russian Federation averaged 3,207 per year (USFWS unpublished data). This mortality estimate includes corrections for under-reported harvest (U.S. only) and struck and lost animals. Harvest has been declining by about 3 percent per year since 2000 and was exceptionally low in the United States in 2012–2014. Resource managers in Russia have concluded that the population has declined and have reduced harvest quotas in recent years accordingly, based in part on the lower abundance estimate generated from the 2006 survey (Kochnev 2004; Kochnev 2005; Kochnev 2010, pers. comm.; Litovka 2015, pers. comm.). The quota in 2000 was 3000 animals; by 2010, it was just 1300 (Shadbolt *et al.* 2014). However, Russian hunters have never reached the quota (Litovka 2015, pers. comm.).

Detailed information on the biology and status of the species, including a revised stock assessment report announced on April 21, 2014 (79 FR 22154), is available at *http://www.fws.gov/alaska/fisheries/mmm/.*

Potential Impacts of the Activities on Pacific Walruses

Proposed cable-laying activities in the Chukchi Sea may encounter Pacific walruses, but encounters in the Beaufort and Bering Seas are unlikely. The Southern Beaufort Sea east of 153° W. is extralimital; encounters are unlikely there. Project activities are scheduled to occur in the northern Bering Sea after mid-July, when most Pacific walruses have moved north into the Chukchi Sea or south to Bristol Bay. No project activities are planned in Bristol Bay or in the Bering Sea south of Nome.

Proposed activities in the Chukchi Sea in July–August have the greatest degree of overlap with areas used by Pacific walruses. Project activities occurring in these areas in September–November may also encounter Pacific walruses. Noise and vessel activities associated with the project have the potential to disrupt normal behavioral patterns including migration, nursing, and feeding. Use of thrusters, echo sounders, and beacon transceivers could generate noise levels capable of causing acoustic harassment near the project area and are discussed in the following section.

Noise

Pacific walruses hear sounds both in air and in water. Kastelein *et al.* (1996) tested the in-air hearing of one individual from 125 hertz (Hz) to 8 kilohertz (kHz) and determined the animal could hear all frequency ranges tested, but the best sensitivity was 250 Hz–2 kHz. Kastelein *et al.* (2002) tested underwater hearing and determined that range of hearing was 1 kHz–12 kHz with greatest sensitivity at 12 kHz. The small sample size of one animal warrants caution; other pinnipeds can hear up to 40 kHz. Many of the noise sources generated by the Quintillion cable project are likely to be audible to Pacific walruses. Exposure to high levels of underwater sound may cause hearing loss in nearby animals and disturbance of animals at greater distances. Sound attenuates in air more rapidly than in water; airborne sound levels likely to be produced by the proposed action are unlikely to cause hearing damage unless animals are very close to the sound source.

Acoustic sources operating during cable laying will include thrusters, plows, jets, ROVs, echo sounders, and positioning beacons. Of these, the dominant source of radiated underwater noise at frequencies less than 200 Hz is propeller cavitation from the vessel propulsion systems (Ross 1976). The cable ships will each maintain dynamic positioning during cable-laying operations by using two 1,500-kW bow thrusters, two 1,500-kW aft thrusters, and one 1,500-kW fore thruster. Sound source measurements have not been conducted specific to the C/S *Ile de Brehat,* but acoustic studies for similar vessels have shown thruster noise measurements of 171–180 dB$_{\rm rms}$ at 1 m (Nedwell *et al.* 2003; Samsung 2009; Deepwater Wind 2012).

Echo sounders, transceivers, and transponders will be used to conduct hydroacoustic surveys of water depth and to guide the position of the plow and ROV. Sound levels produced by these sources can range from 210–226 dB at 1 m, but are generally at frequencies above the hearing sensitivities of Pacific walruses; typical frequencies are 24 kHz–900 kHz. Some surveys use frequencies as low as 50 Hz or as high as 2 megahertz (MHz). Pulses of sound are produced every 1 to 3 seconds in narrow downward-focused beams; there is very little horizontal propagation of noise. Commercial sonar systems may generate lower frequency side-lobes audible to marine mammals, but these are generally produced at sound levels unlikely to cause harm (Deng *et al.* 2014). Depending on the action, the area, and the acoustics involved, sound from multiple sources may combine synergistically or partly cancel out. Cable ships will not operate simultaneously in close proximity to each other (within 10 km).

Marine mammals in general have variable reactions to noise sources, particularly mobile sources such as marine vessels. Potential impacts from noise include displacement from preferred foraging areas, increased stress, energy expenditure, interference with feeding, masking of communications, or temporary hearing loss. Potential acoustic injuries from exposure to high levels of sound may manifest in the form of temporary or permanent changes in hearing sensitivity. The underwater hearing abilities of the Pacific walrus have not been studied sufficiently to develop species-specific criteria for preventing harmful exposure. Sound pressure level thresholds have been developed for other members of the pinniped taxonomic group, above which exposure is likely to cause behavioral responses and injuries (Finneran 2015).

Historically, NOAA has used 190 dB$_{\rm rms}$ as a threshold for predicting injury to pinnipeds and 160 dB$_{\rm rms}$ as a threshold for behavioral impacts from exposure to impulse noise (NMFS 1998; HESS 1999). The behavioral response threshold was developed based primarily on observations of marine mammal responses to airgun operations (*e.g.,* Malme *et al.* 1983a, 1983b; Richardson *et al.* 1986, 1995). Southall *et al.* (2007) assessed relevant studies, found considerable variability among pinnipeds, and determined that exposures between ~90–140 dB generally do not appear to induce strong behavioral responses in pinnipeds in water, but an increasing probability of avoidance and other behavioral effects exists in the 120–160-dB range.

The NOAA 190–dB$_{\rm rms}$ injury threshold is an estimate of the sound level likely to cause a permanent shift in hearing thresholds (permanent threshold shift or PTS). This value was modelled from temporary threshold shifts (TTS) observed in pinnipeds (NMFS 1998; HESS 1999). Southall *et al.* (2007) reviewed the literature and derived behavior and injury thresholds based on peak sound pressure levels of 212 dB (peak) and 218 dB (peak) respectively. Because onset of TTS can vary in response to duration of exposure, Southall *et al.* (2007) also derived thresholds based on sound exposure levels (SEL). Sound exposure level can be thought of as a composite metric that represents both the magnitude of a sound and its duration. The study proposed threshold SELs weighted at frequencies of greatest sensitivities for pinnipeds of 171 dB (SEL) and 186 dB (SEL) for behavioral impacts and injury respectively (Southall *et al.* 2007). Kastak *et al.* (2005) found exposures resulting in TTS in pinniped test subjects ranging from 152–174 dB (183–206 dB SEL). Reichmuth *et al.* (2008) demonstrated a persistent TTS, if not a PTS, after 60 seconds of 184 dB SEL. Kastelein (2012) found small but statistically significant TTSs at approximately 170 dB SEL (136 dB, 60 min) and 178 dB SEL (148 dB, 15 min).

Based on these data, and applying a precautionary approach in the absence of empirical information, we assume it is possible that Pacific walruses exposed to 190–dB or greater sound levels from underwater activities could suffer injury from PTS. Pacific walruses exposed to underwater sound pressure levels greater than 180 dB could suffer temporary shifts in hearing thresholds. Repeated or continuous exposure to sound levels between 160 and 180 dB may also result in TTS, and exposures above 160 dB are more likely to elicit behavioral responses than lower level exposures.

The Service's underwater sound mitigation measures include employing "Protected Species Observers" (PSOs) to establish and monitor 160–dB, 180–dB, and 190–dB isopleth mitigation zones centered on any underwater sound source greater than 160 $\mathrm{dB_{rms}}$. For projects that produce sound levels greater than 180 $\mathrm{dB_{rms}}$, the 180–dB and 190–dB zones are monitored to ensure no marine mammals are in the zone before the sound-producing activity begins and during the activity. The Quintillion project is not expected to produce sound at this level, but the 160–dB zone will be monitored; Pacific walruses in this zone will be assumed to experience Level B take.

Pacific walruses' reactions to noise sources at likely to be variable, depending on the sound levels and frequencies, individuals' prior exposure to the disturbance source, their need or desire to be in the particular habitat or area where they are exposed to the noise, location relative to the disturbance, and whether the disturbance source is visible or odorous. Pacific walruses are typically more sensitive to disturbance when hauled out on land or ice than when they are in the water. The Quintillion cable project will be carried out away from the edge of the seasonal pack ice and terrestrial haulouts. This will minimize potential interactions with large concentrations of Pacific walruses in the project area, which typically favor sea-ice habitats or land-based haulouts.

Relatively minor reactions, such as increased vigilance, are not likely to disrupt biologically important behavioral patterns and, therefore, do not constitute take by harassment, as defined by the MMPA. Reactions such as fleeing a haulout or departing a feeding area have the potential to disrupt biologically significant behavioral patterns, including nursing, feeding, and resting, and may result in decreased fitness for the affected animal. These reactions meet the criteria for Level B harassment under the MMPA. Significant reactions have been documented in response to vessel noise. For example, icebreaking activities in the Chukchi Sea were observed to displace some Pacific walrus groups up to several kilometers (Brueggeman *et al.* 1990) away. Approximately 25 percent of groups on pack ice responded by diving into the water; most reactions occurred within 805m–1 km (0.5–0.6 mi) of the ship. However, groups of hauled-out Pacific walruses beyond these distances generally showed little reaction to icebreaking activities (Brueggeman *et al.* 1990, 1991). Activities producing high levels of noise or occurring in close proximity also have the potential to illicit extreme reactions (Level A harassment) including separation of mothers from young or instigation of stampedes, resulting in death of the offspring or death by trampling respectively.

Cable-laying activities will occur in regions of the Chukchi Sea used by Pacific walruses for foraging. Noise from these activities may cause Pacific walruses to be displaced during feeding, and could have direct effects on food resources. Little research has been conducted on the effects of sound on invertebrates. Mussels, clams, and crabs do not have auditory systems or swim bladders that could be affected by sound pressure, but squid and other invertebrate species have complex statocysts that resemble the otolith organs of fish that may allow them to detect sounds (Budelmann 1992). Normandeau Associates, Inc. (2012) concluded that invertebrates are sensitive to local water movements and to low-frequency particle accelerations generated by sound sources in their close vicinity. Based on these results, impulsive hydroacoustic surveys could acoustically impact local marine communities, but only within a limited area. From an ecological community standpoint, these impacts are considered minor. No significant reduction in quality or availability of Pacific walrus food resources is expected.

The proposed action will include measures to prevent extreme behavioral reactions to project noise and injury from noise exposure. Measures include minimizing probability of encounters by working during times when sea ice is not present and avoiding terrestrial haulouts. Cable vessels will not operate in areas where doing so would allow animals to be exposed to simultaneous noise from more than one ship. Acoustic ensonification zones will be monitored by PSOs during cable laying to document take and during pre- and post-cable-laying activities to maintain at least an 805-m (0.5-mi) distance from Pacific walruses. These measures are expected to reduce the intensity of disturbance events and to minimize the potential for injuries to animals.

Vessel-Based Activities

Pacific walruses may be disturbed by the sights, sounds, and smells of humans, machinery, and equipment associated with the proposed vessel-based activities during Quintillion's project. The potential responses of Pacific walruses to these types of disturbances are highly variable and may depend on the context of the encounter. Responses may include: Altered headings; increased swimming rates; increased vigilance; changes in dive, surfacing, respiration, feeding, and vocalization patterns; and hormonal stress production (*i.e.*, see Richardson *et al.* 1995; Southall *et al.* 2007; Ellison *et al.* 2011). Pacific walruses use the project area for feeding, resting, and migrating, and for in-season travel, and are most likely to be exposed to the proposed activities while travelling or feeding in areas away from the coast. They are most likely to respond by retreating from cable-laying activities.

The proposed cable route is outside of the HSWUA, which will limit the number of walruses exposed to the project activities, but some Pacific walruses may be foraging outside the HSWUA and could be displaced while using these peripheral feeding areas. Pacific walruses that are displaced while foraging in peripheral feeding areas or while traveling between Hanna Shoal and coastal haulouts are likely to expend some additional energy avoiding the project activities. Effects of displacement within foraging areas and from travel routes will depend on the ability of the affected animals to reach and use alternate areas. There are no anticipated events or activities that will restrict availability of or access to other suitable foraging habitat or alternate travel routes during this project.

Pacific walruses may cross paths with cable-laying and support vessels while migrating or traveling to foraging or resting areas. The reaction of Pacific walruses to vessel traffic is dependent upon vessel type, distance, speed, and an animal's previous exposure to disturbances. For example, low-frequency diesel engines have been observed to cause fewer disturbances than high-frequency outboard engines (Fay *et al.* 1984). Pacific walruses may respond to at-sea cable-laying work by exhibiting brief startling reactions or by temporarily vacating the area. There is no long-term biologically significant impact to Pacific walruses expected from the proposed cable-laying activity.

The Chukchi Sea contains important food resources. Trenching for cable burial will impact benthic and epibenthic invertebrates by: (1) Crushing with the plough blade, plough skid, or ROV track; (2) dislodgement onto the surface where they may die; and (3) the settlement of suspended sediment away from the trench where it may clog gills or feeding structures of sessile invertebrates or smother sensitive species (BERR 2008). Recolonization of benthic communities in northern latitudes is slow and may take 10 years or more (Conlan and Kvitek 2005; Beuchel and Gulliksen 2008). Seafloor trenching will leave a lasting impact on the seafloor within the cable corridor, but will have only a minor effect on the benthic community in a local area. Linear trenching of this scale will affect approximately 0.3 percent of each square km intersected by the cable route. This is an insignificant portion of the total seafloor available for Pacific walrus foraging. Further, none of the activity will occur in the HSWUA. The overall effects of cable laying on food resources will be inconsequential to Pacific walruses.

Disturbance that occurs while Pacific walruses are resting at a haulout may have the greatest potential for harmful impacts. Disturbance events in the Chukchi Sea have been known to cause groups to abandon land or ice haulouts and occasionally result in trampling injuries or cow-calf separations, both of which are potentially fatal (USFWS 2015a). Anecdotal observations by Pacific walrus hunters and researchers also suggest that males tend to be more tolerant of disturbances than females (Fay *et al.* 1984). Females with dependent calves are considered least tolerant of disturbance and most likely to flee a haulout. Calves and young animals at terrestrial haulouts are particularly vulnerable to trampling injuries. The risk of stampede-related injuries increases with the number of animals at a haulout.

Quintillion's activities are planned to avoid disturbance of haulouts. Pacific walrus densities in the Chukchi Sea are highest along the edge of the pack ice, and the proposed activities are scheduled to avoid pack ice. The probability of encountering haulouts in pack ice is, therefore, low. Operations may encounter aggregations of Pacific walruses hauled out onto sparse patches of ice or when cable branches are installed at beach landings. Cable end branches will be placed perpendicular to the coastline and adjacent to the respective village to minimize nearshore activities. Landing locations were selected with input from local residents to avoid areas where haulouts may occur. No nearshore work will be done near Point Lay, where large haulouts are likely.

Oil/Fuel Spills

Potential spills could involve fuel, oil, lubricants, solvents, and other substances used aboard the cable ships or support vessels. An oil spill or unpermitted discharge is an illegal act; IHAs do not authorize takes of marine mammals caused by illegal or unpermitted activities. If a spill did occur, the most likely impact upon Pacific walruses would be exposure to spilled oil, which may cause injury, illness, or possibly death depending on degree and duration of exposure and the characteristics of the spilled substance. A large spill could result in a range of impacts from reduced food availability to chronic ingestion of contaminated food. Spill response activities, especially use of dispersants, may increase the cumulative impact of a spill on Pacific walrus habitat by making oil more bioavailable for uptake by filter feeders and benthic invertebrates (*e.g.,* Epstein *et al.* 2000; Hansen *et al.* 2012). However, the overall effect on the environment of spill response activities given a spill are expected to be lower than the level of impact of the spill alone (USFWS 2015b). The effects of a spill event would depend on the amount, substance, and specific circumstances of the spill, but small spills, such as could occur in connection with the activities proposed by Quintillion, are unlikely to have negative impacts on Pacific walruses.

Estimated Incidental Take of Pacific Walruses by Harassment

The Service anticipates that incidental take of Pacific walruses may occur during Quintillion's cable-laying project. Noise, vessels, and human activities could temporarily interrupt feeding, resting, and movement patterns. The project component most likely to result in take is cavitation noise produced by the thrusters during dynamic positioning of the cable-laying vessel. The elevated underwater noise levels may cause short-term, temporary, nonlethal, but biologically significant changes in behavior that the Service considers to be Level B harassment. Other proposed activities, such as the use of an ROV, tug and barge, dive team, and support vessels are considered to have a limited potential for disturbance leading to take.

For non-impulse sounds, such as those produced by the dynamic positioning thrusters during Quintillion's subsea cable-laying operation, the Service uses the 190-$\mathrm{dB_{rms}}$ isopleth to indicate the onset of Level A harassment. The activities are not expected to generate noise above 180 $\mathrm{dB_{rms}}$ within frequencies audible to Pacific walruses; therefore, there is no 180-dB or 190-dB mitigation zone from the proposed activities. No project activities are expected to result in take by Level A harassment.

Quintillion provided calculations to estimate take by Level B harassment based on the estimated number of Pacific walruses that may occur within the 120-dB isopleth produced by the dynamic positioning thrusters during the proposed cable-laying operation. The Service generally associates the 160-dB isopleth with Level B harassment. The estimate of take based on the 120-dB isopleth will account for all animals exposed to sound levels higher than 120 dB, including those exposed to 160 dB or greater. The Service evaluated these calculations to determine whether the necessary MMPA findings could be made per Quintillion's petition, but we expect Quintillion's calculations to overestimate the number of Pacific walruses that will be taken. Quintillion provided a full description of the methodology used to estimate take by harassment in its IHA petition, which is also provided in the following paragraphs.

Exposure Estimates and Take Authorization Request

The estimate of the numbers of Pacific walruses that could be taken by Level B harassment from exposure to thruster noise during cable-laying operations was determined by multiplying the maximum seasonal density of Pacific walruses by the total area in the northern Bering, Chukchi, and southwestern Beaufort Seas (to 153°W) that will be ensonified by sound levels greater than 120 $\mathrm{dB_{rms}}$. The acoustic footprint (total ensonified area) was determined by assuming that dynamic positioning would occur along all trunk and branching lines within the proposed fiber optic cable network, regardless of the cable-laying vessel used or activity conducted.

Various acoustic investigations have modeled distances to the 120-dB isopleth for water depths similar to where Quintillion would be operating with results ranging between 1.4–3.5 km (Samsung 2009; Deepwater Wind 2013). However, these ranges were based on conservative modeling that included maximum parameters and worst-case assumptions. Hartin *et al.* (2011) measured dynamic positioning noise from the 104-m (341–ft) Drill Ship *Fugro Synergy* while operating in the Chukchi Sea. It used 2,500-kW thrusters (more powerful than those used on the C/S *Ile de Brehat*) and produced frequencies of 110–140 Hz. The 90th percentile radius to the 120-dB isopleth was 2.3 km (1.4 mi). Because this radius is a measured value from the same water body where Quintillion's cable-laying operation would occur, as opposed to a conservatively modeled value from the Atlantic Ocean, this value is used in estimating exposures.

The sum total of submerged cable length is 1,904 km (1,183 mi), but total cable length within Pacific walrus habitat (west of 153° W.) is 1,691 km (1,051 mi). Assuming that the radius to the 120-dB isopleth is 2.3 km (1.4 mi), the total ensonified area encompasses an area 1,691 km (1,051 mi) in length and 4.6 km (2.8 mi) in width (4.6 = 2 × 2.3 km) or 7,780 km^2 (3,004 mi^2) total (4.6 × 1,691 ≈ 7,780). The area of the 120-dB isopleth at any one instant may be up to 16.6 km^2 (6.2 mi^2) centered on the cable-laying vessel (radius(r) = 2.3 km; Area = πr^2). A total of 49.8 km^2 (18.6 mi^2) may be ensonified at one time if all three cable-laying vessels are in operation in different locations.

The seasonal distribution of Pacific walruses in the project area is associated with the distribution and extent of broken pack ice (Fay *et al.* 1984; Garlich-Miller *et al.* 2011; Aerts *et al.* 2014). During years of high summer sea-ice cover in the Chukchi Sea, most Pacific walruses are expected to remain with the ice and feed in areas like Hanna Shoal. During low-ice years when the edge of the pack ice recedes north from the Chukchi Sea to the Arctic Basin, where waters are too deep to forage, Pacific walruses typically leave the ice and haul out on beaches (such as near Point Lay).

The best available at-sea density estimates come from Aerts *et al.* (2014), who conducted shipboard surveys for marine mammals in the Chukchi Sea in 2008–2013. Their highest recorded summer densities were in the low-ice years of 2009 (0.040 walrus/km^2) and 2013 (0.041 walrus/km^2). During the heavy-ice years of 2008 and 2012, densities were 0.001 and 0.006 walrus/km^2, respectively. Given the continuing trend for light summer ice conditions, it is assumed that 2016 will be similar to 2013. Therefore, the 2013 density estimate of 0.041 walrus/km^2 is used in the exposure estimates.

The number of Pacific walruses potentially exposed to harassment by the Quintillion cable project was estimated by multiplying the seasonal density (0.041 walrus/km^2) by the total area (7,780 km^2) that would be ensonified by thruster noise greater than 120 dB_{rms}. This resulted in an estimate of 319 Pacific walruses (0.041 × 7,780 ≈ 319). While this number was generated using a conservative density value from low-ice years, it does not take into account the potential for encounters with large groups of Pacific walruses moving between Hanna Shoal and Point Lay, or near the Wainwright and Barrow shore landings. During marine mammal observations made for offshore oil and gas activities in the Chukchi Sea in 2015, PSOs recorded 500 sightings of 1,397 individual Pacific walruses (Ireland and Bisson 2016). The average number of walruses per observation was only 1.5, but on several occasions, groups of more than 100 animals were observed. The maximum group size was 243 animals. Taking into consideration the possibility that any encounter might include large groups, Quintillion estimated that up to 500 Pacific walruses may be taken as a result of all activities.

This level of take by harassment is small relative to the most recent stock abundance estimate for the Pacific walrus. A take level of 500 represents only 0.39 percent of the best available estimate of the current population size of 129,000 animals (Speckman *et al.* 2011) (500/129,000 ≈ 0.0039).

Potential Impacts on the Stock of Pacific Walrus

Although 500 Pacific walruses (~0.39 percent of the population) are estimated to be potentially taken (*i.e.,* potentially disturbed) by Level B harassment by means of exposure to sound levels of 160–190 dB, the expected take is unlikely to have consequences for the health, reproduction, or survival of affected animals. The major source of disturbance is likely to be production of sound by propeller cavitation during dynamic positioning by the cable-laying vessels. Sound production is not expected to reach levels capable of causing harm. Additionally, animals in the area are not expected to incur hearing impairment (TTS or PTS) or non-auditory physiological effects. Level A harassment (harassment that has the potential to injure Pacific walruses) is not authorized. Pacific walruses exposed to sound produced by the project are likely response to proposed activities with temporary behavioral modification or displacement. With the adoption of the mitigation measures required by this proposed IHA, the Service concludes that the only anticipated effects from noise generated by the proposed action would be short-term behavioral alterations of small numbers of Pacific walruses.

Vessel-based activities could temporarily interrupt the feeding, resting, and movement of Pacific walruses. Because offshore activities are expected to move through the Chukchi Sea, impacts associated with cable laying are likely to be temporary and localized. The anticipated effects include short-term behavioral reactions and displacement of small numbers of Pacific walruses in the vicinity of active operations. Areas affected by the proposed action will be small compared to the regular movement patterns of the population indicating that animals will be capable of retreating from or avoiding the affected areas. Animals that encounter the proposed activities may exert more energy than they would otherwise due to temporary cessation of feeding, increased vigilance, and retreat from the project area, but would be expected to tolerate this without measurable effects on health or reproduction. Adoption of the measures specified in Mitigation and Monitoring are expected to reduce the intensity of disturbance events and minimize the potential for injuries to animals.

In sum, no injuries or mortalities are anticipated to occur as a result of Quintillion's subsea cable-laying operation, and none will be authorized. The takes that are anticipated and would be authorized are expected to be limited to short-term Level B harassment in the form of brief startling reactions or temporary displacement. No long-term biologically significant impacts to Pacific walruses are expected.

Potential Impacts on Subsistence Uses

The MMPA allows Alaska Natives to harvest Pacific walruses for subsistence purposes or for the purposes of creating authentic Native articles of handicraft and clothing, provided this is accomplished in a non-wasteful manner. The proposed cable-laying activities will occur within the marine subsistence areas used by Alaska Natives from the villages of Nome, Wales, Diomede, Kotzebue, Kivalina, Point Hope, Point Lay, Wainwright, Barrow, and Nuiqsut, all of which annually hunt Pacific walruses, except Nuiqsut. Between 2006 and 2015, approximately 1,080 Pacific walruses were harvested annually in Alaska (USFWS unpublished data). The years 2013–2015 were low harvest years; annual harvest from 2006–2012 was 1,308 per year. These estimates are of reported harvest only and have not been corrected for struck and lost animals or underreporting. Most of the harvest (87 percent) was taken by the villages of Gambell and Savoonga on St. Lawrence Island, located 135 km (84 mi) south of the geographic region of the Quintillion cable project.

The villages within the project area harvested an average of 81 Pacific walruses per year from 2006–2015. The small village of Diomede (population of ~115) harvested 26 percent of these (~21 per year). Diomede is located on Little Diomede Island in the center of the Bering Strait. Twice a year the vanguard of the walrus population passes through the Strait when migrating between wintering and summering grounds providing harvest opportunities for Diomede hunters. Pacific walruses will also occasionally haul out on Little Diomede Island during the summer and fall (Garlich-Miller and Burn 1999).

Relative to the village population size (556), Pacific walruses are also an important staple for Wainwright inhabitants. From 2006–2015, approximately 26 Pacific walruses were taken annually. Wainright also harvests beluga and bowhead whales. The small village of Wales (population ~145), located on the eastern edge of the Bering Strait, harvested an average of six Pacific walruses each year (USFWS unpublished data). Nome also harvested six Pacific walruses per year, and Barrow harvested 14 per year from 2006–2015. Nome and Barrow both have populations of approximately 4,000 people, and Pacific walrus is not as important in the subsistence diet as other resources.

Kotzebue, Kivalina, Point Hope, and Point Lay each harvested fewer than five Pacific walruses annually from 2006–2015, suggesting harvest of this species in these villages is more opportunistic than focused. The communities of Savoonga, Brevig Mission, Chefornak, Elim, Gambell, Hooper Bay, King Island, Kipnuk, Shaktoolik, Shishmaref, Teller, Togiak, and Toksook Bay all harvested one or more per year on average from 2006–2015, but are outside of the geographic region of the proposed action.

There are only a few locations where the proposed project area could overlap with local subsistence harvest areas. These include the portion of the route passing between the villages of Diomede and Wales, and the branching line into Wainwright. The proposed route is expected to pass about 25 km (16 mi) east of Little Diomede Island. Presence of ice is needed for any spring Pacific walrus hunts from Diomede, and the Quintillion cable-laying vessel cannot operate in the presence of ice.

Pacific walruses are harvested from Wainwright and Barrow during July and August from drifting ice floes (Bacon *et al.* 2009). Most are killed within 32 km (20 mi) of shore, but some are taken by both villages as far as 64 km (40 mi) offshore (SRB&A 2012). The Quintillion cable route will pass within 30 km (19 mi) of both villages, and the branching lines will go directly to both Wainwright and Barrow. However, given the hazard ice floes pose to the cable-laying project, Quintillion will not be operating within either village's subsistence hunt area when seasonal sea ice is present. Thus, the cable-laying project is not expected to affect the annual Pacific walrus hunts by either Wainwright or Barrow. For the remaining villages, the annual harvest is relatively low and generally occurs when ice is present, or occurs well away from the proposed cable route (in the case of Point Lay, the route will run well offshore of the village).

Based on the proposed cable-laying timetable relative to the seasonal timing of the various village harvest periods, an overlap in cable laying and Pacific walrus hunting is not expected. However, Quintillion will continue to work closely with the Eskimo Walrus Commission (EWC) and the affected villages to minimize any effects cable-laying activities might have on subsistence harvest, including scheduling the laying of branching lines to avoid periods when Pacific walruses are present.

Mitigation and Monitoring

In order to issue an incidental take authorization under section 101(a)(5)(D) of the MMPA, the Service must, where applicable, set forth the permissible methods of take and other means of effecting the least practicable impact on the Pacific walrus and its habitat, and on the availability of the species or stock for subsistence uses. Particular attention must be paid to habitat areas of importance, including haulouts and feeding areas. The Service evaluated the project, its potential impacts, and the range of avoidance, mitigation, and minimization measures that could be applied. Monitoring and mitigation measures were developed that will minimize the potential impacts and ensure the least practicable impact to Pacific walruses. As part of these mitigation measures, Quintillion will communicate closely with the EWC and the villages to ensure subsistence harvest is not disrupted. A Plan of Cooperation (POC) has been developed and will be implemented to structure and facilitate coordination with subsistence users. Work will be scheduled to minimize activities in hunting areas during subsistence harvest periods. Quintillion has also developed a Marine Mammal Monitoring and Mitigation Plan (4MP). Habitat areas where Pacific walruses engage in particularly sensitive activities (such as feeding or resting at haulouts) will be avoided. Adaptive measures, such as temporal or spatial limitations, will be applied in response to the presence of Pacific walruses. These documents will be available for public review as specified in **ADDRESSES.**

Avoidance

For the proposed Quintillion subsea cable-laying operations in the Bering, Chukchi, and Beaufort Seas and coastal lands of Alaska, the primary means of minimizing potential consequences for Pacific walrus and subsistence users is routing the cable to avoid concentration areas and important prey habitat. Most of the main trunk line will be laid 30–150 km (19–93 mi) offshore, thereby avoiding nearshore Pacific walrus concentrations and terrestrial haulouts. Where cable end branches will come ashore, landings will be conducted at right angles to the coastline and immediately adjacent to the respective village (except at Oliktok Point where no village exists) to minimize nearshore activities and avoid areas where haulouts may occur. No work will be done near Point Lay, where large haulouts are likely, or near Hanna Shoal, where feeding aggregations may occur. Cable-laying activities will not be performed by multiple vessels simultaneously where doing so would create overlapping ensonification zones. The proposed action will not occur north of the Bering Strait until July 1 to allow Pacific walruses the opportunity to disperse from the confines of the spring lead system and to minimize interactions with subsistence hunters. Quintillion's operations must avoid sea ice for safety reasons. In doing so, Quintillion will avoid ice habitat used by Pacific walruses. The cable-laying operation will occur at a slow speed of 600 m/hr (0.37 mph), and it is, therefore, highly unlikely that cable-laying activities could cause injury. Collisions between vessels and marine mammals are rare, and when they do occur, they usually involve fast-moving vessels.

Vessel-Based Protected Species Observers (PSOs)

Measures included in the proposed IHA to monitor and reduce the frequency and severity of behavioral responses to the activities will include visual observation by vessel-based PSOs, acoustic monitoring, and adaptive measures in response to observations. The primary purpose of these mitigation measures is to detect marine mammals and avoid vessel interactions during the pre- and post-cable-laying activities. Due to the nature of the activities, the vessel will not be able to shut down or change speed or direction during cable-laying operations.

Quintillion has proposed to employ PSOs during cable-laying operations to monitor zones of ensonification where the received sound level is 120 dB or greater. Observers will conduct vessel-based monitoring for Pacific walruses during all daylight periods of operation throughout the cable-laying operation. The duties of PSOs will include: Watching for marine mammals and identifying Pacific walruses; recording their numbers, locations, distances, and reactions to the survey operations; and documenting take by harassment. A sufficient number of trained PSOs will be required onboard each survey vessel to achieve 100 percent monitoring coverage during all periods of cable-laying operations in daylight with a maximum of 4 consecutive hours on watch and a maximum of 12 hours of watch time per day, per PSO. Nighttime observations will be made opportunistically using night-vision equipment.

Each vessel will have an experienced field crew leader to supervise the PSO team and will contain individuals with prior experience as marine mammal monitoring observers, including experience specific to Pacific walrus observations. New or inexperienced PSOs would be paired with an experienced PSO so that the quality of marine mammal observations and data recording is kept consistent. Resumes for candidate PSOs will be made available for the Service to review. All observers will have completed a training course designed to familiarize individuals with monitoring and data collection procedures. The PSOs shall be provided with Fujinon 7 × 50 or equivalent binoculars. Laser range finders (Leica LRF 1200 or equivalent) will be available to assist with distance estimation.

All location, weather, and marine mammal observation data will be recorded onto a standard field form or database. Global positioning system and weather data will be collected at the beginning and end of a monitoring period and at every half-hour in between. Position data will also be recorded at the change of an observer or the sighting of a Pacific walrus. Enough position data will be collected to map an accurate charting of vessel travel. Observations of Pacific walruses will also include group size and composition (adults/juveniles), behavior, distance from vessel, presence in any applicable ensonification zone, and any apparent reactions to the project activities. Data forms or database entries will be made available to the Service upon request.

Acoustic Monitoring

Quintillion plans to conduct sound source verification and contribute to passive acoustic monitoring efforts. Acoustic injury to Pacific walruses can occur if received noise levels exceed 190 dB. The cable-laying activities are not expected to produce noise levels capable of acoustic injury, and Quintillion is not requesting authorization of take by Level A harassment. Therefore, no shutdown zones will be necessary for this activity. However, Level B take may occur due to exposure to sound at greater than 160-dB levels. For this reason, observers must monitor the 160-B ensonification zone for the presence of Pacific walruses. Quintillion has committed to monitoring the 120-dB zone for marine mammals. The 160-dB zone is well within the 120-dB zone and, therefore, will be included in the monitoring area.

Sound source verification will be conducted during early-season operation of one cable-lay ship and anchor-handling tug. Results will be used to calibrate the 120-dB and 160-dB ensonification zones. If sound source verification indicates that sound levels produced during operations will be higher than expected (greater than 190 dB_{rms} at frequencies less than 40 kHz), Quintillion will coordinate with the Service to evaluate additional mitigation options.

Passive acoustic monitoring will be conducted by the 2016 joint Arctic Whale Ecology Study (ARCWEST)/ Chukchi Acoustics, Oceanography, and Zooplankton Study Extension (CHAOZ–X) with support from Quintillion. The current mooring locations for the passive acoustic monitoring portion of the joint program align closely with the proposed Quintillion cable-lay route. Acoustic data from these locations in 2016 will provide information on the distribution and composition of the marine mammal community and the acoustic effects of the cable-lay activity on the local environment where the route passes close to these stations.

Adaptive Measures

When the cable ships are traveling in Alaskan waters to and from the project area (before and after completion of cable laying), and during all travel by support vessels, operators will implement the following measures:

- Avoid potential interaction with any and all Pacific walruses by taking reasonable precautions such as changing speed or course when Pacific walruses are observed within 805 km (0.5 mi). Changes in speed or course will be achieved gradually to avoid abrupt maneuvers whenever possible.
- Do not approach Pacific walruses within 805 km (0.5 mi).
- Reduce speed to less than 2.6 meters per second (m/s) (5 kn) when visibility drops (such as during inclement weather, rough seas, or at night) to avoid the likelihood of collision with Pacific walruses. During cable laying, the normal vessel travel speed is less than 2.6 m/s (5 kn).
- Vessels may not be operated in such a way as to separate members of a group of Pacific walruses from other members of the group.
- Activities are not planned near known haulouts, but if Pacific walruses are observed on land, vessels will maintain a 1.6 km (1 mi) separation distance.
- Any behavioral response indicating more than Level B take of a Pacific walrus due to project activities shall be reported to the Service within 48 hours, including separation of mother from young, stampeding haulouts, injured animals, and animals in acute distress.

Measures To Reduce Impacts to Subsistence Users

The Service requires holders of an IHA to cooperate with the Service and other designated Federal, State, and local agencies to monitor the impacts of proposed activities on marine mammals and subsistence users. Quintillion has coordinated with the Service, NOAA—Fisheries, and the Army Corps of Engineers, along with communities and subsistence harvest organizations. Specifically, Quintillion has coordinated with EWC, Barrow Whaling Captains Association members and board, the Community of Wainwright, Wainwright Whaling Captains, Point Hope Community, Tikigaq Whaling Captains, the Northwest Arctic Borough, Kotzebue City Management, the Community of Kotzebue, Maniilaq Association, Kawerak Inc., the Nome Community, and Kuukpik Corporation. Communications will continue throughout the project and may include public service announcements on KBRW and KOTZ radio stations, messaging on the Alaska Rural Communications Service television network, newsletters, and 1–800 comment lines. At the end of the cable installation process, Quintillion will conduct community meetings at the affected landing villages identified in this document to discuss and summarize project completion. In coordination with these agencies and organizations, Quintillion has agreed to the following actions to minimize effects on subsistence harvest by Alaska Native communities:

- Plan routes in offshore waters away from nearshore subsistence harvest areas.
- Schedule operations to avoid conflict with subsistence harvest.
- Develop and implement a POC to coordinate communication.
- Participate in the Automatic Identification System for vessel tracking to allow the cable-laying fleet to be located in real time.
- Distribute a daily report by email to all interested parties. Daily reports will include vessel activity, location, subsistence/local information, and any potential hazards.

Reporting Requirements

Holders of an IHA must keep the Service informed of the impacts of authorized activities on Pacific walruses by: (1) Notifying the Service at least 48 hours prior to commencement of activities; (2) immediately reporting any occurrence of injury or mortality due to project activities; (3) submitting project reports; and (4) notifying the Service upon project completion or at the end of the work season.

Weekly reports will be submitted to the Service each Thursday during the weeks that cable-laying activities take place. The reports will summarize project activities, monitoring efforts conducted by PSOs, results of sound source verification, Pacific walruses detected, the number of Pacific walruses exposed to sound levels greater than 160 dB, and any behavioral reactions to project activities.

A technical report will be submitted to the Service within 90 days after the end of the project or the end of the open-water season, whichever comes first. The report will describe all monitoring activities conducted during cable-laying activity and provide results. The report will include the following:

- Summary of monitoring effort (total hours of monitoring, activities monitored, number of PSOs).
- Summary of project activities completed and additional work yet to be done.
- Analyses of the factors influencing visibility and detectability of marine mammals (*e.g.,* sea state, number of observers, and fog/glare).
- Discussion of location, weather, ice cover, sea state, and other factors affecting the presence and distribution of Pacific walruses.
- Number, location, distance/direction from the vessel, and initial behavior of any sighted Pacific walruses upon detection.
- Dates, times, locations, heading, speed, weather, and sea conditions (including sea state and wind force), as well as description of the specific cable-laying activity occurring at the time of the Pacific walrus observation.
- Estimated distance from the animal or group at closest approach and at the end of the encounter.
- An estimate of the number of Pacific walruses that have been exposed to the thruster noise (based on visual observation) at received levels greater than or equal to 120 dB_{rms} and 160 dB_{rms} with a description of the responses (changes in behavior).
- Estimates of uncertainty in all take estimates, with uncertainty expressed by the presentation of confidence limits, a minimum-maximum, posterior probability distribution, or another applicable method, with the exact approach to be selected based on the sampling method and data available.
- A description of the mitigation measures implemented during project activities and their effectiveness for minimizing the effects of the proposed action on Pacific walruses.
- An analysis of the effects of survey operations on Pacific walruses.
- Occurrence, distribution, and composition of Pacific walrus sightings, including date, water depth, numbers, age/size/gender categories (if determinable), group sizes, visibility, location of the vessel, and location of the animal (or distance and direction to the animal from the vessel) in the form of electronic database or spreadsheet files.
- A discussion of any specific Pacific walrus behaviors of interest.

Notification of Injured or Dead Marine Mammals

In the unexpected event that the specified activity causes the take of a Pacific walrus in a manner not authorized by the IHA such as an injury or mortality (*e.g.,* ship-strike), Quintillion must report the incident to the Service within 24 hours. The report will include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Name and type of vessel involved;
- Vessel's speed during and leading up to the incident;
- Description of the incident;
- Description of all sound sources used in the 24 hours preceding the incident;
- Water depth;
- Environmental conditions (*e.g.,* wind speed and direction, cloud cover, and visibility);
- Description of all Pacific walrus observations in the 24 hours preceding the incident;
- Description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

In the event that Quintillion discovers an injured or dead Pacific walrus, and the lead PSO determines that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Quintillion must report the incident to the Service within 48 hours of the discovery. Quintillion will provide photographs or video footage (if available) or other documentation to the Service.

Mitigation Conclusions

The Service has carefully evaluated Quintillion's proposed mitigation measures and considered a range of other measures of ensuring that the cable project will have the least practicable impact on Pacific walruses and their habitat. Our evaluation considered the following: (1) The manner in which, and the degree to which, the successful implementation of the measures are expected to minimize adverse impacts to Pacific walruses; (2) the proven or likely efficacy of the measures to minimize adverse impacts as planned; and (3) the practicability of the measures for applicant implementation.

The expected effects of the prescribed mitigation measures are as follows:

- Avoidance of injury or death of Pacific walruses.
- Reduction in the numbers of Pacific walruses exposed to activities expected to result in the take of marine mammals.
- Reduction in the number of times individuals would be exposed to project activities.
- A reduction in the intensity of exposures to activities expected to result in the take of Pacific walruses.
- Avoidance or minimization of adverse effects to Pacific walrus habitat, especially haulout areas, sea ice, and foraging areas.
- An increase in the probability of detecting Pacific walruses through vessel-based monitoring, allowing for

more effective implementation of mitigation measures.

- Reduction in the likelihood of affecting Pacific walruses in a manner that would alter their availability for subsistence uses.

Based on our evaluation of the proposed mitigation measures, the Service has preliminarily determined that these measures provide the means of effecting the least practicable impact on Pacific walruses and their habitat, including feeding areas and haulouts. These measures will also minimize any effects the project will have on the availability of the species or stock for subsistence uses.

Findings

Small Numbers

For small take analyses, the statute and legislative history do not expressly require a specific type of numerical analysis, leaving the determination of "small" to the agency's discretion. In this case, we propose a finding that the Quintillion project will affect up to 500 Pacific walruses, and that this constitutes a small number of animals. Factors considered in our small numbers determination include the number of Pacific walruses in the affected area, the size of the affected area relative to available habitat, and the expected efficacy of mitigation measures.

First, the number of Pacific walruses inhabiting the proposed impact area is small relative to the size of the Pacific walrus population. The potential exposures for the 2016 cable-laying period, based on estimated density plus an additional allowance for the clumped distribution of Pacific walruses, is approximately 500 animals. This is about 0.39 percent of the population size of 129,000 estimated by Speckman *et al.* (2011).

Second, the area where the proposed activities would occur is a relatively small fraction of the available habitat of the Pacific walrus. Cable-laying activities will have temporary impacts to Pacific walrus habitat along a 1,691-km (1,051-mi) linear corridor of marine waters and coastal land of Alaska. Sound levels greater than 120 $\mathrm{dB_{rms}}$ may be produced by propeller cavitation in an area of up to 16.6 km^2 (6.2 mi^2) centered on each cable ship. Up to three ships may operate in different locations at one time, resulting in a combined area of ensonification up to 49.8 km^2 (18.6 mi^2). Trenching of the seafloor may disturb the benthos along the cable route, affecting a total area of approximately 6 km^2 (2.3 mi^2). These impacts will be temporary and localized, and will not impede the use of an area after the project activities in that area are complete.

Third, monitoring requirements and mitigation measures are expected to limit the number of incidental takes. The cable route will avoid sea ice, terrestrial haulouts, and important feeding habitat. Adaptive mitigation measures will be applied by the support fleet and when cable ships are in transit. These measures will include changes in speed or course when Pacific walruses could come within 805 m (0.5 mi), and are expected to help prevent take by Level A harassment and to minimize take by Level B harassment. Activities will be monitored by PSOs, and unexpected impacts and will be reported to the Service. No take by injury or death is anticipated or authorized. Monitoring and reporting will allow the Service to reanalyze and refine future take estimates and mitigation measures as activities continue in Pacific walrus habitat in the future. Should the Service determine, based on monitoring and reporting, that the effects are greater than anticipated the authorization may be modified, suspended, or revoked.

For these reasons, we propose a finding that the Quintillion project will involve takes by Level B harassment of only a small number of animals.

Negligible Impact

The Service proposes a finding that any incidental take by harassment resulting from the proposed Quintillion cable-laying operation cannot be reasonably expected to, and is not reasonably likely to, adversely affect the Pacific walrus through effects on annual rates of recruitment or survival, and would, therefore, have no more than a negligible impact on the species or stock. In making this finding, we considered the best available scientific information, including: (1) The biological and behavioral characteristics of the species; (2) the most recent information on species distribution and abundance within the area of the proposed action; (3) the potential sources of disturbance during the proposed action; and (4) the potential responses of Pacific walruses to this disturbance. In addition, we reviewed material supplied by the applicant, other operators in Alaska, our files and datasets, data acquired from NOAA—Fisheries, published reference materials, and Pacific walrus experts.

Pacific walruses are likely to respond to proposed activities with temporary behavioral modification or displacement. These reactions are unlikely to have consequences for the health, reproduction, or survival of affected animals. The major source of disturbance is likely to be production of sound by propeller cavitation during dynamic positioning by the cable-laying vessels. Sound production is not expected to reach levels capable of causing harm, and Level A harassment (harassment that has the potential to injure Pacific walruses) is not authorized. Sound source verification will be conducted to ensure that this assessment is accurate.

Responses of Pacific walruses to disturbance would most likely include diving or swimming away from the sound source, which may cause temporary interruption of foraging, resting, or other natural behaviors. Affected animals are expected to resume normal behaviors soon after exposure, with no lasting consequences. Thus, although 500 Pacific walruses (~0.39 percent of the population) are estimated to be potentially taken (*i.e.*, potentially disturbed) by Level B harassment from exposure to sound levels of 160–190 dB, we do not expect this type of harassment to affect annual rates of recruitment or survival or result in adverse effects on the species or stock.

Our proposed finding of negligible impact applies to incidental take associated with the proposed activities as mitigated by the avoidance and minimization measures. These mitigation measures are designed to minimize interactions with and impacts to Pacific walruses. These measures, and the monitoring and reporting requirements, are required for the validity of our finding and are a necessary component of the IHA.

For these reasons, we propose a finding that the Quintillion project will have a negligible impact on Pacific walruses.

Impact on Subsistence

We propose a finding that the anticipated harassment caused by the proposed activities would not have an unmitigable adverse impact on the availability of Pacific walruses for taking for subsistence uses. In making this finding, we considered the timing and location of the proposed activities and the timing and location of subsistence harvest activities and patterns, as reported through the Service's Marking, Tagging, and Reporting Program in the area of the proposed action. We also considered the applicant's consultation with potentially affected subsistence communities and proposed measures for avoiding impacts to subsistence harvest.

Required Determinations

National Environmental Policy Act (NEPA)

We have prepared a draft Environmental Assessment (EA) (see **ADDRESSES**) in accordance with the NEPA (42 U.S.C. 4321 *et seq.*). We have preliminarily concluded that approval and issuance of an authorization for the nonlethal, incidental, unintentional take by Level B harassment of small numbers of Pacific walruses in Alaska during cable-laying activities conducted by Quintillion would not significantly affect the quality of the human environment, and that the preparation of an environmental impact statement for these actions is not required by section 102(2) of NEPA or its implementing regulations.

Endangered Species Act

Under the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*) all Federal agencies are required to ensure the actions they authorize are not likely to jeopardize the continued existence of any threatened or endangered species or result in destruction or adverse modification of critical habitat. The range-wide status of Pacific walruses was reviewed in response to a 2008 petition to list this species. On February 10, 2011 (76 FR 7634), the listing of walruses was found to be warranted, but precluded due to higher priority listing actions (*i.e.,* walrus is a candidate species). Consistent with established agency policy, the Service's Ecological Service program will evaluate whether the effects of the proposed activities will jeopardize the continued existence of the Pacific walrus prior to issuance of an IHA. Our evaluation and finding will be made available on the Service's Web site at *http://www.fws.gov/alaska/fisheries/mmm/iha.htm.*

Government-to-Government Relations With Native American Tribal Governments

In accordance with the President's memorandum of April 29, 1994, "Government to Government Relations with Native American Tribal Governments" (59 FR 22951), Executive Order 13175, Department of the Interior Secretarial Order 3225 of January 19, 2001 (Endangered Species Act and Subsistence Uses in Alaska (Supplement to Secretarial Order 3206)), Department of the Interior Secretarial Order 3317 of December 1, 2011 (Tribal Consultation and Policy), Department of the Interior Memorandum of January 18, 2001 (Alaska Government-to-Government Policy), the Department of the Interior's manual at 512 DM 2, and the Native American Policy of the U.S. Fish and Wildlife Service, dated January 20, 2016, we acknowledge our responsibility to communicate and work directly on a Government-to-Government basis with federally recognized Alaska Natives Tribes in developing programs for healthy ecosystems, to seek their full and meaningful participation in evaluating and addressing conservation concerns for listed species, to remain sensitive to Alaska Native culture, and to make information available to Alaska Natives.

Furthermore, and in accordance with Department of the Interior Policy on Consultation with Alaska Native Claims Settlement Act of 1971 (ANCSA) Corporations, dated August 10, 2012, we likewise acknowledge our responsibility to communicate and work directly with ANCSA Corporations in evaluating and addressing conservation concerns for listed species, to remain sensitive to Alaska Native culture, and to make information available to ANSCA Corporations.

We have evaluated possible effects of the proposed activities on federally recognized Alaska Native Tribes. Through the IHA process identified in the MMPA, the applicant presented a communication process, culminating in a POC with the Native communities most likely to be affected, and engaged these communities in numerous informational meetings.

To facilitate co-management activities, the Service maintains cooperative agreements with the EWC and the Qayassiq Walrus Commission (QWC). The cooperative agreements fund a wide variety of management issues, including co-management operations, biological sampling programs, harvest monitoring, collection of Native knowledge in management, international coordination on management issues, cooperative enforcement of the MMPA, and development of local conservation plans. To help realize mutual management goals, the Service, EWC, and QWC hold meetings to discuss future expectations and outline a shared vision of co-management.

Through various interactions and partnerships, we have determined that the issuance of this proposed IHA is appropriate. We invite continued discussion about improving our coordination and information exchange, including through the IHA/POC process, as may be requested by Tribes or other Native groups.

Proposed Authorization

The Service proposes to issue an IHA for the nonlethal, incidental, unintentional take by Level B harassment of small numbers of Pacific walruses during cable-laying activities in the marine waters of Alaska and impacted coastal communities, as described in this document and in the applicant's petition. We neither anticipate nor propose authorization for intentional take or take by injury or death. The final IHA would be effective immediately after the date of issuance through November 15, 2016.

The final IHA would also incorporate the mitigation, monitoring, and reporting requirements described in this proposal. The applicant would be expected and required to implement and fully comply with those requirements. If the nature or level of activity changes or exceeds that described in this proposal and in the IHA petition, or the nature or level of take exceeds that projected in this proposal, the Service will reevaluate its findings. The Secretary may modify, suspend, or revoke the authorization if the findings are not accurate or the mitigation, monitoring, and reporting requirements described herein are not being met.

Dated: June 3, 2016.

Brian S. Glaspell,

Acting Regional Director, Alaska Region.

[FR Doc. 2016–14847 Filed 6–22–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R7–MB–2016–N0109; FF09M21200–156–FXMB1231099BPP0]

Information Collection Request Sent to the Office of Management and Budget (OMB) for Approval; Alaska Migratory Bird Subsistence Harvest Household Survey

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (U.S. Fish and Wildlife Service) have sent an Information Collection Request (ICR) to OMB for review and approval. We summarize the ICR below and describe the nature of the collection and the estimated burden and cost. This information collection is scheduled to expire on June 30, 2016. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control

number. However, under OMB regulations, we may continue to conduct or sponsor this information collection while it is pending at OMB.

DATES: You must submit comments on or before July 25, 2016.

ADDRESSES: Send your comments and suggestions on this information collection to the Desk Officer for the Department of the Interior at OMB–OIRA at (202) 395–5806 (fax) or *OIRA_Submission@omb.eop.gov* (email). Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail), or *hope_grey@fws.gov* (email). Please include "1018–0124" in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Hope Grey at *hope_grey@fws.gov* (email) or 703–358–2482 (telephone). You may review the ICR online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION:

Information Collection Request

OMB Control Number: 1018–0124.

Title: Alaska Migratory Bird Subsistence Harvest Household Survey.

Service Form Number(s): 3–2380, 3–2381–1, 3–2381–2, 3–2381–3, and 3–2381–4.

Type of Request: Extension of a currently approved collection.

Description of Respondents: Households within subsistence eligible areas of Alaska.

Respondent's Obligation: Voluntary.

Frequency of Collection: Annually for Tracking Sheet and Household Consent; three times annually for Harvest Report.

Activity	Number of respondents	Number of responses	Completion time per response (minutes)	Total annual burden hours
3–2380, Tracking Sheet and Household Consent	2,553	2,553	5	213
3–2381–1 thru 3–2381–4, Harvest Report (three seasonal sheets)	2,300	6,900	5	575
Totals	4,853	9,453	....	788

Abstract: The Migratory Bird Treaty Act of 1918 (16 U.S.C. 703–712) and the Fish and Wildlife Act of 1956 (16 U.S.C. 742d) designate the Department of the Interior as the key agency responsible for managing migratory bird populations that frequent the United States and for setting harvest regulations that allow for the conservation of those populations. These responsibilities include gathering accurate geographical and temporal data on various characteristics of migratory bird harvest. We use harvest data to review regulation proposals and to issue harvest regulations.

The Migratory Bird Treaty Act Protocol Amendment (1995) (Amendment) provides for the customary and traditional use of migratory birds and their eggs for subsistence use by indigenous inhabitants of Alaska. The Amendment states that its intent is not to cause significant increases in the take of species of migratory birds relative to their continental population sizes. A submittal letter from the Department of State to the White House (May 20, 1996) accompanied the Amendment and specified the need for harvest monitoring. The submittal letter stated that the Service, the Alaska Department of Fish and Game (ADF&G), and Alaska Native organizations would collect harvest information cooperatively within the subsistence eligible areas. Harvest survey data help to ensure that customary and traditional subsistence uses of migratory birds and their eggs by indigenous inhabitants of Alaska do not significantly increase the take of species of migratory birds relative to their continental population sizes.

Between 1989 and 2004, we monitored subsistence harvest of migratory birds using annual household surveys in the Yukon-Kuskokwim Delta, which is the region of highest subsistence bird harvest in the State of Alaska. In 2004, we began monitoring subsistence harvest of migratory birds in subsistence eligible areas Statewide. The Statewide harvest assessment program helps to track trends and changes in levels of harvest. The harvest assessment program relies on collaboration among the Service, the ADF&G, and a number of Alaska Native organizations.

We gather information on the annual subsistence harvest of about 60 bird species/species categories (ducks, geese, swans, cranes, upland game birds, seabirds, shorebirds, and grebes and loons) in the subsistence eligible areas of Alaska. The survey covers 11 regions of Alaska, which are further divided into subregions. We survey the regions and villages in a rotation schedule to accommodate budget constraints and to minimize respondent burden. The survey covers spring, summer, and fall harvest in most regions.

In collaboration with Alaska Native organizations, we hire local resident surveyors to collect the harvest information. The surveyors list all households in the villages to be surveyed and provide survey information and harvest report forms to randomly selected households that have agreed to participate in the survey. To ensure anonymity of harvest information, we identify households by a numeric code. The surveyor visits households three times during the survey year. At the first household visit, the surveyor explains the survey purposes and invites household participation. The surveyor returns at the end of the season of most harvest and at the end of the two other seasons combined to help the household complete the harvest report form.

We have designed the survey methods to streamline procedures and reduce respondent burden. We use the following forms for household participation:

- FWS Form 3–2380 (Tracking Sheet and Household Consent). The surveyor visits each household selected to participate in the survey to provide information on the objectives and to obtain household consent to participate. The surveyor uses this form to record consent and track subsequent visits for completion of harvest reports.
- FWS Forms 3–2381–1, 3–2381–2, 3–2381–3, and 3–2381–4 (Harvest Report). The Harvest Report has drawings of bird species most commonly available for harvest in the different regions of Alaska, with fields for writing down the numbers of birds and eggs taken. There are four versions of this form: Interior Alaska, North Slope, Southern Coastal Alaska, and Western Alaska. This form has a sheet for each season surveyed, and each sheet has fields for the household code, community name, harvest year, date of completion, and comments.

Comments Received and Our Responses

Comments: On December 3, 2015, we published in the **Federal Register** (80 FR 75685) a notice of our intent to request that OMB renew approval for this information collection. In that notice, we solicited comments for 60 days, ending on February 1, 2016. We did not receive any comments.

Request for Public Comments

We again invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask OMB and us in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: June 17, 2016.

Tina A. Campbell,

Chief, Division of Policy, Performance, and Management Programs, U.S. Fish and Wildlife Service.

[FR Doc. 2016–14843 Filed 6–22–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2016–N079; FXES11120800000–156–FF08EVEN00]

Low-Effect Habitat Conservation Plan for the Morro Shoulderband Snail; Mammen Parcel, Community of Los Osos, San Luis Obispo County, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have received an application from Renee and Kurt Mammen for a 10-year incidental take permit (ITP) under the Endangered Species Act of 1973, as amended. The application addresses the potential for "take" of the federally endangered Morro shoulderband snail likely to result incidental to the construction and maintenance of a single-family residence on an existing legal parcel, associated infrastructure, and use of an existing access road in the unincorporated community of Los Osos, San Luis Obispo County, California. We invite comments from the public on the application package, which includes a draft low-effect habitat conservation plan (HCP) and draft low-effect screening form and environmental action statement, which constitutes our proposed National Environmental Policy Act (NEPA) compliance.

DATES: To ensure consideration, please send your written comments by July 25, 2016.

ADDRESSES: You may download a copy of the draft HCP and draft low-effect screening form and environmental action statement on the internet at *http://www.fws.gov/ventura/*, or you may request copies of the documents by U.S. mail to our Ventura office, or by phone (see **FOR FURTHER INFORMATION CONTACT**). Please address written comments to Stephen P. Henry, Field Supervisor, Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, CA 93003. You may alternatively send comments by facsimile to (805) 644–3958.

FOR FURTHER INFORMATION CONTACT: Julie M. Vanderwier, Senior Fish and Wildlife Biologist, at the Ventura office address or by phone at (805) 644–1766.

SUPPLEMENTARY INFORMATION: We have received an application for an incidental take permit (ITP) pursuant to section 10(a)(1)(B) of the Endangered Species Act (Act; 16 U.S.C. 1531 *et seq.*). The application addresses take of the federally endangered Morro shoulderband snail (*Helminthoglypta walkeriana*) likely to occur incidental to the construction and maintenance of a single-family residence and associated infrastructure and use of an existing access road. The requested permit term is 10 years and the permit would be subject to renewal. We invite comments from the public on the application package. Issuance of an ITP pursuant to this HCP has been determined to be eligible for a categorical exclusion under NEPA.

Background

The Morro shoulderband snail was listed as endangered on December 15, 1994 (59 FR 64613). Section 9 of the Act and its implementing regulations (16 U.S.C. 1531 *et seq.*) prohibit the take of fish or wildlife species listed as endangered or threatened. Under the Act, "take" is defined to include the following activities: "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct" (16 U.S.C. 1532). Under section 10(a)(1)(B) of the Act, we may issue permits to authorize take of listed species if it is incidental to other lawful activities and not the purpose of carrying out that activity. The Code of Federal Regulations provides those regulations governing incidental take permits for threatened and endangered species at 50 CFR 17.32 and 17.22. Issuance of an incidental take permit must not jeopardize the existence of any federally listed fish, wildlife or plant species.

The Applicant's Proposed Project

The project involves the construction and maintenance of a single-family residence and associated infrastructure along with use of an existing access road to a legal parcel in the Bayview Heights subdivision of Los Osos, County of San Luis Obispo, California. The HCP provides the support necessary for the Service to issue an incidental take permit (ITP) that would authorize take, in this instance, of the Morro shoulderband snail (*Helminthoglypta walkeriana*). The County of San Luis Obispo requires demonstration that the property owner is in compliance with the Endangered Species Act of 1973, as amended (Act) as part of their permitting requirements.

The draft HCP contains two alternatives to the proposed action: "No Action" and "Project Redesign." Under the "No Action" alternative, an ITP for the Mammen single-family residence would not be issued. The Mammen single-family residence could not legally be built and the mitigation fee would not be available to contribute to recovery actions for Morro shoulderband snail. Since the property is privately owned, there are ongoing economic considerations (*e.g.*, payment of property taxes) associated with continued ownership of a property and its intended use. The sale of the property for purposes (*e.g.*, as a conservation easement) other than the identified activity is not economically feasible. For these reasons, the "No Action" alternative has been rejected.

The "Project Redesign" alternative would involve design of a project that would reduce or avoid altogether take of Morro shoulderband snail. This alternative was not selected, due to the parcel's small size and marginal value to the long-term conservation of the Morro shoulderband snail of habitat on site. A reduction or redesign of the project footprint would not meet the applicants' needs and would not significantly reduce the effects of the taking of Morro shoulderband snail such that there would be a greater benefit to species survival and recovery. For these reasons, the "Project Redesign" alternative has also been rejected.

Our Preliminary Determination

We have determined that the applicants' proposal will have a minor or negligible effect on the Morro shoulderband snail and that the HCP qualifies for processing as a low-effect plan consistent with our Habitat Conservation Planning Handbook (November 1996). Three criteria form the basis for our determination: (1) The proposed project as described in the HCP would result in minor or negligible effects on federally listed, proposed, and/or candidate species and their habitats; (2) implementation of the HCP would result in minor negligible effects on other environmental values or resources; and (3) HCP impacts, considered together with those of other past, present, and reasonably foreseeable future projects, would not result in cumulatively significant effects. It is our preliminary determination that HCP approval and ITP issuance qualify for categorical exclusion under the NEPA (42 U.S.C. 4321 *et seq.*), as provided by the Department of the Interior implementing regulations in part 46 of title 43 of the Code of Federal Regulations (43 CFR 46.205, 46.210, and 46.215). However, we may revise our determination based upon review of public comments received in response to this notice.

Next Steps

We will evaluate the permit application, including the draft HCP and comments we receive, to determine whether it meets the requirements of section 10(a)(1)(B) of the Act. We will also evaluate whether issuance of the ITP would comply with section 7of the Act by conducting an intra-Service consultation pursuant to section 7(a)(2).

Public Review

We request comments from the public regarding our preliminary determination that the applicant's proposal will have a minor or negligible effect on the Morro shoulderband snail and that the HCP qualifies for processing as a low-effect. We will evaluate comments received and make a final determination regarding whether the application meets the requirements of section 10(a)(1)(B) of the Act. We will incorporate the results of our intra-Service consultation, in combination with the above findings, in our final analysis to determine whether to issue the ITP. If all of our requirements are met, we will issue the ITP to the applicant. Permit issuance would not occur less than 30 days after the date of this notice.

Public Comments

If you wish to comment on the permit application, HCP, and associated documents, you may submit comments by any one of the methods provided in **ADDRESSES**.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public view, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under section 10(c) of the Act and the NEPA public involvement regulations (40 CFR 1500.1(b), 1500.2(d), and 1506.6).

Dated: June 15, 2016.

Stephen P. Henry,

Field Supervisor, Ventura Fish and Wildlife Office, Ventura, California.

[FR Doc. 2016–14853 Filed 6–22–16; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[167 A2100DD/AAKC001030/ A0A501010.999900]

Renewal of Agency Information Collection for Energy Resource Development Program Grants

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of submission to OMB.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Bureau of Indian Affairs (BIA) has submitted to the Office of Management and Budget (OMB) a request for renewal of the collection of information for grants under the Office of Indian Energy and Economic Development, Energy and Mineral Development Program, authorized by OMB Control Number 1076–0174. This information collection expires June 30, 2016.

DATES: Interested persons are invited to submit comments on or before July 25, 2016.

ADDRESSES: Please submit your comments to the Desk Officer for the Department of the Interior at the Office of Management and Budget, by facsimile to (202) 395–5806 or you may send an email to: *OIRA_Submission@omb.eop.gov.* Also please send a copy of your comments to Rebecca Naragon, U.S. Department of the Interior, Office of Indian Energy and Economic Development, 1951 Constitution Avenue NW., MS–16–SIB, Washington, DC 20245; email: *Rebecca.Naragon@bia.gov.*

FOR FURTHER INFORMATION CONTACT: Rebecca Naragon, U.S. Department of the Interior, Office of Indian Energy and Economic Development, 1951 Constitution Avenue NW., MS–16–SIB, Washington, DC 20245; email: *Rebecca.Naragon@bia.gov.* You may review the information collection request online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Energy Policy Act of 2005, 25 U.S.C. 3502(a)(2)(B) authorizes the Secretary of the Interior to provide grants to assist Indian Tribes in the development of energy resources and further the goal of Indian self-determination.

The Office of Indian Energy and Economic Development (IEED) administers and manages the energy resource development grant program under the Energy and Minerals Development Program (EMDP). Congress may appropriate funds to EMDP on a year-to-year basis. When funding is available, IEED may solicit proposals for energy resource development projects from Indian Tribes and Tribal energy resource development organizations for use in carrying out projects to promote the integration of energy resources, and to process, use or develop those energy resources on Indian land. The projects may be in the areas of exploration, assessment, development, feasibility, or market studies. Indian Tribes that would like to apply for an EMDP grant must submit an application that includes certain information, and must assist IEED by providing information in support of any National Environmental Policy Act (NEPA) analyses. Upon acceptance of an application, a Tribe must then submit one—to two—page quarterly progress reports summarizing events, accomplishments, problems and/or results in executing the project. Quarterly reports assist IEED staff with project monitoring of the EMDP program and ensure that projects are making adequate progress in achieving the project's objectives.

II. Request for Comments

The Bureau of Indian Affairs (BIA) requests your comments on this collection concerning: (a) The necessity of this information collection for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) The accuracy of the agency's estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) Ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) Ways we could minimize the burden of the collection of the information on the respondents.

Please note that an agency may not conduct or sponsor, and an individual need not respond to, a collection of information unless it displays a valid OMB Control Number.

It is our policy to make all comments available to the public for review at the location listed in the **ADDRESSES** section. Before including your address, phone number, email address or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

III. Data

OMB Control Number: 1076–0174.

Title: Energy and Mineral Development Program Grants.

Brief Description of Collection: Indian Tribes that would like to apply for an EMDP grant must submit an application that includes certain information. A complete application must contain a current, signed Tribal resolution that provides sufficient information to authorize the project and comply with the terms of the grant; a proposal describing the planned activities and deliverable products; and a detailed budget estimate. The IEED requires this information to ensure that it provides funding only to those projects that meet the goals of the EMDP and purposes for which Congress provides the appropriation. Upon acceptance of an application, a Tribe must then submit one—to two—page quarterly progress reports summarizing events, accomplishments, problems and/or results in executing the project.

Type of Review: Extension without change of currently approved collection.

Respondents: Federally recognized Indian Tribes with Indian land.

Number of Respondents: 53 applicants per year; 34 project participants each year.

Frequency of Response: Once per year for applications; 4 times per year for progress reports.

Obligation to Respond: Responses are required to receive or maintain a benefit.

Estimated Time per Response: 40 hours per application; 1.5 hours per progress report.

Estimated Total Annual Hour Burden: 2,324 hours (2,120 for applications and 204 for progress reports).

Estimated Total Annual Non-Hour Collar Cost: $0.

Elizabeth K. Appel,

Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2016–14841 Filed 6–22–16; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Public Meetings of the Invasive Species Advisory Committee

AGENCY: Office of the Secretary, Interior.

ACTION: Notice.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act, notice is hereby given of meetings of the Invasive Species Advisory Committee (ISAC). Comprised of 26 nonfederal invasive species experts and stakeholders from across the nation, the purpose of the Advisory Committee is to provide advice to the National Invasive Species Council, as authorized by Executive Order 13112, on a broad array of issues related to preventing the introduction of invasive species and providing for their control and minimizing the economic, ecological, and human health impacts that invasive species cause. The Council is co-chaired by the Secretary of the Interior, the Secretary of Agriculture, and the Secretary of Commerce. The duty of the Council is to provide national leadership regarding invasive species issues.

Purpose of Meeting: To convene the full ISAC and to provide expert input and recommendations to NISC federal agencies and their partners on invasive species matters of national importance. While in session, ISAC will: (1) Consider adoption of the white paper entitled, *Addressing the Needs of Classical Biocontrol Programs,* as proposed by ISAC's Subcommittee on Control and Management; (2) receive update of progress in Federal agency implementation of prior recommendations from ISAC as well as new Federal initiatives as outlined in the National Invasive Species Council Management Plan; and, (3) commence work on NISC priority initiatives through subcommittees (task teams) focused on: (a) Strengthening Federal/State coordination; (b) strengthening Federal/Tribal coordination; (c) identifying risks and opportunities for the application of gene editing as a means of eradication or controlling invasive species; (d) assessing implications of and needs to regulate invasive species that impact infrastructure; and, (e) assessing implications of and needs to regulate invasive species that impact wildlife health. The meeting agenda is available on the NISC Web site at *http://www.doi.gov/invasivespecies/isac/isac-meetings.cfm.* Supplemental reference materials will be posted on or about Monday, June 27, 2016.

DATES: Meeting of the Invasive Species Advisory Committee: Tuesday, July 12, 2016: 8:30 a.m. to 5:00 p.m.; Wednesday, July 13, 2016: 8:30 a.m. to 5:30 p.m.; Thursday, July 14, 2016; 8:00 a.m.–12:00 p.m.

ADDRESSES: Smithsonian Institution National Museum of the American Indian, 4th and Independence Avenue SW., Washington, DC 20560. The general session will be held in the Conference Center (4th Floor). NOTE: All meeting participants and interested members of the public must register their attendance online at *http://goo.gl/forms/aCThKkCEqr0rOuaA3.* Attendees must pass through security screening upon entering the facility.

FOR FURTHER INFORMATION CONTACT: Kelsey Brantley, National Invasive Species Council Program Specialist and ISAC Coordinator, Phone: (202) 208–4122; Fax: (202) 208–4118, email: *Kelsey_Brantley@ios.doi.gov.*

Dated: June 14, 2016.

Jamie K. Reaser,

Executive Director, National Invasive Species Council (NISC) Secretariat.

[FR Doc. 2016–14860 Filed 6–22–16; 8:45 am]

BILLING CODE 4334–63–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[16X LLAK980600.L1820000.XX0000. LXSIARAC0000]

Notice of Cancellation of Public Meeting, BLM Alaska Resource Advisory Council

AGENCY: Bureau of Land Management, Alaska State Office, Interior.

ACTION: Notice of cancellation of public meeting.

SUMMARY: The Bureau of Land Management (BLM) Alaska Resource Advisory Council (RAC) has been cancelled.

DATES: The meeting was to be held June 28–30, 2016, at the Arctic Interagency Visitor Center, Dalton Highway, Coldfoot, Alaska 99701.

FOR FURTHER INFORMATION CONTACT: June Lowery, RAC Coordinator, BLM Alaska State Office, 222 W. 7th Avenue #13, Anchorage, AK 99513; *jlowery@blm.gov;* 907–271–3130.

SUPPLEMENTARY INFORMATION: The 15-member council advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management in Alaska.

Dated: June 16, 2016.

Bud C. Cribley,

State Director.

[FR Doc. 2016–14849 Filed 6–22–16; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[16XL1109AF LLUT030000 L16100000.PH0000 241A]

Notice of Grand Staircase-Escalante National Monument Advisory Committee Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the Department of the Interior, Bureau of Land Management (BLM), Grand Staircase-Escalante National Monument Advisory Committee (GSENMAC) will meet as indicated below.

DATES: The GSENM MAC will meet Friday, August 5, 2016, (10 a.m.–4 p.m.) in Escalante, Utah.

ADDRESSES: The Committee will meet at the Escalante Interagency Visitor Center, located at 755 West Main Street, Escalante, Utah.

FOR FURTHER INFORMATION CONTACT: Larry Crutchfield, Public Affairs Officer, Grand Staircase-Escalante National Monument, Bureau of Land Management, 669 South Highway 89A, Kanab, Utah 84741; phone (435) 644–1209.

SUPPLEMENTARY INFORMATION: The 15-member GSENMAC was appointed by the Secretary of Interior on January 23, 2016, pursuant to the Monument Management Plan, the Federal Land Policy and Management Act of 1976 (FLPMA), and the Federal Advisory Committee Act of 1972 (FACA). As specified the Committee charter, the GSENMAC may be requested to: (1) Gather and analyze information, conduct studies and field examinations, seek public input or ascertain facts to develop recommendations concerning the use and management of the Monument; (2) Review programmatic documents including the annual Monument Manager's Reports, and Monument Science Plans to provide recommendations on the achievement of the Management Plan objectives; (3) Compile monitoring data and assess and advise the DFO of the extent to which the Plan objectives are being met; (4) Make recommendations on Monument protocols and applicable planning projects to achieve the overall objectives are being met; (5) Review appropriate research proposals and make recommendations on project necessity and validity; (6) Make recommendations regarding allocation of research funds through review of research and project proposals as well as needs identified through the evaluation process; (7) Consult and make recommendations on issues such as protocols for specific projects, *e.g.,* vegetation restoration methods or standards for excavation and curation of artifacts and objects; and/or (8) Prepare an annual report summarizing the Committee's activities and accomplishments of the past year, and make recommendations for future needs and activities.

Topics to be discussed by the GSENMAC during this meeting include new member orientation (MAC Charter, By-laws, FACA committee guidelines and responsibilities), the ongoing Livestock Grazing Management Plan Amendment and Associated Environmental Impact Statement (LGMPA/AEIS), GSENM division reports, future meeting dates and other matters as may reasonably come before the GSENMAC.

The entire meeting is open to the public. Members of the public are welcome to address the Committee at 3:00 p.m., local time, on August 5, 2016. Depending on the number of persons wishing to speak, a time limit could be established. Interested persons may make oral statements to the GSENMAC during this time or written statements may be submitted for the GSENMAC's consideration. Written statements can be sent to: Grand Staircase-Escalante National Monument, Attn.: Larry Crutchfield, 669 South Highway 89A, Kanab, Utah, 84741. Information to be distributed to the GSENMAC is requested 10 days prior to the start of the GSENMAC meeting.

All meetings are open to the public; however, transportation, lodging, and meals are the responsibility of the participating public.

Raul Morales,

Acting State Director.

[FR Doc. 2016–14852 Filed 6–22–16; 8:45 am]

BILLING CODE 4310–DQ–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR02054000, 16XR0687NA, RX.18527901.3000000]

Central Valley Project Improvement Act Water Management Plans

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of availability.

SUMMARY: The Bureau of Reclamation has made available to the public the Water Management Plans for four entities. For the purpose of this announcement, Water Management Plans (Plans) are considered the same as Water Conservation Plans. Reclamation is publishing this notice in order to allow the public an opportunity to review the Plans and comment on the preliminary determinations.

DATES: Submit written comments on the preliminary determinations on or before July 25, 2016.

ADDRESSES: Send written comments to Ms. Charlene Stemen, Bureau of Reclamation, 2800 Cottage Way, MP–410, Sacramento, CA 95825; or via email at *cstemen@usbr.gov.*

FOR FURTHER INFORMATION CONTACT: To be placed on a mailing list for any subsequent information, please contact Ms. Charlene Stemen at the email address above or at 916–978–5281 (TDD 978–5608).

SUPPLEMENTARY INFORMATION: To meet the requirements of the Central Valley Project Improvement Act of 1992 and the Reclamation Reform Act of 1982, the Bureau of Reclamation developed and published the Criteria for Evaluating Water Management Plans (Criteria). Each of the four entities listed below has developed a Plan that has been evaluated and preliminarily determined to meet the requirements of these Criteria. The following Plans are available for review:

- City of Coalinga
- Kern Tulare Water District
- Sacramento River Settlement Contractors, which include the following districts:
    - Anderson-Cottonwood Irrigation District
    - Glen-Colusa Irrigation District
    - Meridian Farms Water Company
    - Natomas Central Mutual Water Company
    - Princeton-Cordova-Glen Irrigation District
    - Provident Irrigation District
    - Reclamation District No. 108
    - Reclamation District No. 1004
    - Sutter Mutual Water Company
- San Benito County Water Agency

We are inviting the public to comment on our preliminary (*i.e.*, draft) determination of Plan adequacy. Section 3405(e) of the Central Valley Project Improvement Act (Title 34 Pub. L. 102–575), requires the Secretary of the Interior to establish and administer an office on Central Valley Project water conservation best management practices that shall "develop criteria for evaluating the adequacy of all water conservation plans developed by project contractors, including those plans required by Section 210 of the Reclamation Reform Act of 1982." Also, according to Section 3405(e)(1), these criteria must be developed "with the purpose of promoting the highest level of water use efficiency reasonably achievable by project contractors using best available cost-effective technology and best management practices." These criteria state that all parties (Contractors) that contract with Reclamation for water supplies (municipal and industrial contracts over 2,000 acre-feet and agricultural contracts over 2,000 irrigable acres) must prepare a Plan that contains the following information:

1. Description of the District;
2. Inventory of Water Resources;
3. Best Management Practices (BMPs) for Agricultural Contractors;
4. BMPs for Urban Contractors;
5. Plan Implementation;
6. Exemption Process;
7. Regional Criteria; and
8. Five-Year Revisions

Reclamation evaluates Plans based on these criteria. A copy of these Plans will be available for review at Reclamation's Mid-Pacific Regional Office, 2800 Cottage Way, MP–410, Sacramento, CA 95825. Our practice is to make comments, including names and home addresses of respondents, available for public review. If you wish to review a copy of these Plans, please contact Ms. Stemen.

Public Disclosure

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: June 13, 2106.

Richard J. Woodley,

Regional Resources Manager, Mid-Pacific Region, Bureau of Reclamation.

[FR Doc. 2016–14654 Filed 6–22–16; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–249 and 731–TA–262, 263, and 265 (Fourth Review)]

Iron Construction Castings From Brazil, Canada, and China; Scheduling of Full Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of full reviews pursuant to the Tariff Act of 1930 ("the Act") to determine whether revocation of the countervailing duty order on heavy iron construction castings from Brazil, the antidumping duty order on heavy iron construction castings from Canada, and the antidumping duty orders on iron construction castings from Brazil and China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. The Commission has determined to exercise its authority to extend the review period by up to 90 days.

DATES: *Effective Date:* June 17, 2016.

FOR FURTHER INFORMATION CONTACT: Porscha Stiger (202–205–3241), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On January 4, 2016, the Commission determined that responses to its notice of institution of the subject five-year reviews were such that full reviews should proceed (81 FR 1967, January 14, 2016); accordingly, full reviews are being scheduled pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)). A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements are available from the Office of the Secretary and at the Commission's Web site.

Participation in the reviews and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in these reviews as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of the reviews need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the reviews.

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these reviews available to authorized applicants under the APO issued in the reviews, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the reviews. A party granted access to BPI following publication of the Commission's notice of institution of the reviews need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the reviews will be placed in the nonpublic record on October 3, 2016, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the reviews beginning at 9:30 a.m. on Thursday, October 20, 2016, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before October 11, 2016. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should participate in a prehearing conference to be held on October 13, 2016, at the U.S. International Trade Commission Building, if deemed necessary. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), 207.24, and 207.66 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party to the reviews may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is October 11, 2016. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is October 31, 2016. In addition, any person who has not entered an appearance as a party to the reviews may submit a written statement of information pertinent to the subject of the reviews on or before October 31, 2016. On November 18, 2016, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before November 28, 2016, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's Handbook on E-Filing, available on the Commission's Web site at *http://edis.usitc.gov,* elaborates upon the Commission's rules with respect to electronic filing.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

The Commission has determined that these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the reviews period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: June 20, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–14878 Filed 6–22–16; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1174–1175 (Review)]

Seamless Refined Copper Pipe and Tube From China and Mexico; Scheduling of Full Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of full reviews pursuant to the Tariff Act of 1930 ("the Act") to determine whether revocation of the antidumping duty orders on seamless refined copper pipe and tube from China and Mexico would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. The Commission has determined to exercise its authority to extend the review period by up to 90 days.

DATES: *Effective Date:* June 17, 2016.

FOR FURTHER INFORMATION CONTACT: Lawrence Jones (202–205–3358), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background—On January 4, 2016, the Commission determined that responses to its notice of institution of the subject five-year reviews were such that full reviews should proceed (81 FR 1967, January 14, 2016); accordingly, full reviews are being scheduled pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)). A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements are available from the Office of the Secretary and at the Commission's Web site.

Participation in the reviews and public service list—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in these reviews as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of these reviews need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the reviews.

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these reviews available to authorized applicants under the APO issued in the reviews, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the reviews. A party granted access to BPI following publication of the Commission's notice of institution of the reviews need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report—The prehearing staff report in the reviews will be placed in the nonpublic record on September 22, 2016, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

Hearing—The Commission will hold a hearing in connection with the reviews beginning at 9:30 a.m. on Tuesday, October 11, 2016, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before October 3, 2016. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should participate in a prehearing conference to be held on October 7, 2016, at the U.S. International Trade Commission Building, if deemed necessary. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), 207.24, and 207.66 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions—Each party to the reviews may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is September 30, 2016. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is October 20, 2016. In addition, any person who has not entered an appearance as a party to the reviews may submit a written statement of information pertinent to the subject of the reviews on or before October 20, 2016. On November 8, 2016, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before November 10, 2016, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's Handbook on E-Filing, available on the Commission's Web site at *http://edis.usitc.gov,* elaborates upon the Commission's rules with respect to electronic filing.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

The Commission has determined that these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the reviews period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: June 20, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–14891 Filed 6–22–16; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–308–310, and 520–521 (Fourth Review)]

Carbon Steel Butt-Weld Pipe Fittings From Brazil, China, Japan, Taiwan, and Thailand; Scheduling of Expedited Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 ("the Act") to determine whether revocation of the antidumping duty orders on carbon steel butt-weld pipe fittings from Brazil, China, Japan, Taiwan, and Thailand would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: *Effective Date:* June 6, 2016.

FOR FURTHER INFORMATION CONTACT: Michael Szustakowski ((202) 205–3169), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for these reviews may be viewed on the

Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On June 6, 2016, the Commission determined that the domestic interested party group response to its notice of institution (81 FR 10656, March 1, 2016) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews.[1] Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).[2]

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Staff report.—A staff report containing information concerning the subject matter of the reviews will be placed in the nonpublic record on June 30, 2016, and made available to persons on the Administrative Protective Order service list for these reviews. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in section 207.62(d) of the Commission's rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,[3] and any party other than an interested party to the reviews may file written comments with the Secretary on what determinations the Commission should reach in the reviews. Comments are due on or before July 6, 2016 and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by July 6, 2016. However, should the Department of Commerce extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on E-Filing,* available on the Commission's Web site at *http://edis.usitc.gov,* elaborates upon the Commission's rules with respect to electronic filing.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: June 20, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–14883 Filed 6–22–16; 8:45 am]

BILLING CODE 7020–02–P

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[1] A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's Web site.

[2] Chairman Broadbent and Commissioner Johanson found that additional circumstances existed to warrant full reviews, and voted to conduct full reviews of the antidumping duty orders.

[3] The Commission has found the responses submitted by Weldbend Corporation and a joint response to the notice from Tube Forgings of America, Inc., Mills Iron Works, Inc., and Hackney Ladish, Inc., to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

INTERNATIONAL TRADE COMMISSION

[USITC SE–16–022]

Government in the Sunshine Act Meeting Notice

CHANGE OF TIME TO GOVERNMENT IN THE SUNSHINE MEETING

AGENCY HOLDING THE MEETING: United States International Trade Commission.

DATE: June 22, 2016.

ORIGINAL TIME: 11:00 a.m.

NEW TIME: 9:30 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

In accordance with 19 CFR 201.35(d)(2)(i), the Commission hereby gives notice that the Commission has determined to change the time of the meeting of June 22, 2016, from 11:00 a.m. to 9:30 a.m.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting. Earlier notification of this change was not possible.

By order of the Commission.

Dated: June 20, 2016.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2016–14950 Filed 6–21–16; 11:15 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (NIJ) Docket No. 1714]

Draft Test Procedures for the Gun Safety Technology Challenge

AGENCY: National Institute of Justice, Justice.

ACTION: Notice and request for comments.

SUMMARY: The National Institute of Justice (NIJ) seeks feedback from the public on the draft failure definition and scoring criteria (FDSC) developed for the Gun Safety Technology Challenge, published here: *http://www.nij.gov/funding/pages/fy16-gun-safety-challenge.aspx.* Evaluation of the test data will employ failure definition (FD) and scoring criteria (SC) to draw conclusions regarding the performance of the submitted firearms or firearms accessories. The document describes the FD and SC that will be used to "score" test events that occur during the testing of handguns, such as pistols and revolvers, in the Challenge.

DATES: Comments must be received by 5 p.m. Eastern Time on August 8, 2016.

How to Respond and What to Include: The draft FDSC document in both Word and pdf formats can be found here: *http://www.nij.gov/funding/pages/fy16-gun-safety-challenge.aspx.* To submit comments, please send an email to *gunsafetytechnology@usdoj.gov.* Please indicate the page number, section number, and the line number associated with each comment. Comments may also be provided as a markup of the Word document. Please provide contact information with the submission of comments.

SUPPLEMENTARY INFORMATION: NIJ was tasked with supporting the President's Plan to Reduce Gun Violence, specifically:

> The President is directing the Attorney General to work with technology experts to review existing and emerging gun safety technologies, and to issue a report on the availability and use of those technologies. In addition, the Administration will issue a challenge to the private sector to develop innovative and cost-effective gun safety technology and provide prizes for those technologies that are proven to be reliable and effective.

In support of this Executive action, NIJ has conducted a technology assessment and market survey of existing and emerging gun safety technologies that would be of interest to the law enforcement and criminal justice communities and others with an interest in gun safety and advanced firearm technology. These firearms or firearms accessories can be understood to use integrated components that exclusively permit an authorized user or set of users to operate or fire the gun and automatically deactivate it under a set of specific circumstances, reducing the chances of accidental or purposeful use by an unauthorized user. The integrated gun safety technology may include different authentication technologies, such as radio frequency identification and fingerprint sensors.

A report published in June 2013 by NIJ entitled *A Review of Gun Safety Technologies* (*https://www.ncjrs.gov/pdffiles1/nij/242500.pdf*) examined existing and emerging gun safety technologies, and their availability and use, to provide a comprehensive perspective on firearms with integrated advanced safety technologies. Following the report, NIJ published a **Federal Register** Notice (*https://federalregister.gov/a/2014-27368*) to receive information regarding which firearms and firearms accessories, that incorporate advanced safety technologies, could be made available by industry for testing and evaluation in the Challenge.

NIJ now seeks an objective demonstration of the reliability of firearms available today with advanced gun safety technology integrated into the firearm. The reliability of firearms with integrated advanced safety technologies has been cited as a concern regarding the potential performance and user acceptance of products that may incorporate such technologies, as discussed in the 2013 NIJ report. It is anticipated that the results of the Challenge will provide a basis to improve the general understanding of whether the addition of a smart gun technology does or does not significantly reduce the reliability of the firearm system compared to existing firearms. It is believed that this is the first effort to apply a methodology to provide a rigorous and scientific assessment of the technical performance characteristics of these types of firearms.

With this Challenge, manufacturers and developers of (1) firearms that incorporate advanced safety technologies or (2) firearms accessories utilizing advanced safety technologies that are intended to modify firearms were able to submit their products for testing and evaluation. The Challenge is designed to proceed in an escalated manner in three stages, including an informational and safety review, light duty single product testing, and more heavy duty expanded product testing. To assess the reliability of smart gun technology, the U.S. Army Aberdeen Test Center (ATC) plans to perform firearm testing and evaluation. The Challenge was published on October 7, 2015, and closed to submissions on January 5, 2016.

NIJ hopes to better understand the effect of smart gun technology on the reliability of the firearm versus the same or similar firearms without the added safety technology. This Challenge seeks "apples to apples" comparisons to the greatest extent possible. Testing and evaluation is designed to prioritize the collection and use of data that can substantiate conclusions about the relative performance of firearms, so that firearms with and without advanced gun safety technology that are similar with respect to type, form factor, caliber, and other physical characteristics are tested and evaluated using a common methodology and equivalent ammunition. Testing and evaluation is not designed to provide comparison of test results against absolute performance requirements or safety criteria, but rather to provide a meaningful comparison of test results of one firearm against another similar firearm, or a firearm with and without a relevant safety accessory. NIJ recently sought feedback from the public on the draft test procedures developed for the Gun Safety Technology Challenge, published here: *https://federalregister.gov/a/2016-10121*. That document describes test methods to provide a basis to determine whether the addition of a smart gun technology does or does not significantly reduce the reliability of the firearm system compared to existing firearms.

Nancy Rodriguez,

Director, National Institute of Justice.

[FR Doc. 2016–14925 Filed 6–22–16; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Advisory Board on Toxic Substances and Worker Health: Subcommittee on Industrial Hygienists (IH) & Contract Medical Consultants (CMC) and Their Reports

AGENCY: Office of Workers' Compensation Programs, Labor.

ACTION: Announcement of meeting of the Subcommittee on IH & CMC and Their Reports of the Advisory Board on Toxic Substances and Worker Health (Advisory Board) for the Energy Employees Occupational Illness Compensation Program Act (EEOICPA).

SUMMARY: The subcommittee will meet via teleconference on July 18, 2016, from 2:00 p.m. to 4:00 p.m. Eastern Time.

For Press Inquiries Contact: For press inquiries: Ms. Amanda McClure, Office of Public Affairs, U.S. Department of Labor, Room S–1028, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–4672; email *mcclure.amanda.c@dol.gov.*

SUPPLEMENTARY INFORMATION: The Advisory Board is mandated by Section 3687 of EEOICPA. The Secretary of Labor established the Board under this authority and Executive Order 13699 (June 26, 2015). The purpose of the Advisory Board is to advise the Secretary with respect to: (1) The Site Exposure Matrices (SEM) of the Department of Labor; (2) medical guidance for claims examiners for claims with the EEOICPA program, with respect to the weighing of the medical evidence of claimants; (3) evidentiary requirements for claims under Part B of EEOICPA related to lung disease; and (4) the work of industrial hygienists and staff physicians and consulting physicians of the Department of Labor and reports of such hygienists and physicians to ensure quality, objectivity, and consistency. The Advisory Board sunsets on December 19, 2019. This subcommittee is being assembled to gather data and begin working on advice under Area #4, IH & CMC and Their Reports.

The Advisory Board operates in accordance with the Federal Advisory

Committee Act (FACA) (5 U.S.C. App. 2) and its implementing regulations (41 CFR part 102–3).

Agenda: The tentative agenda for the Subcommittee on IH & CMC and Their Reports meeting includes:

- Defining the issues and scope of the subcommittee's topic area: the work of industrial hygienists and staff physicians and consulting physicians and their reports to ensure quality, objectivity and consistency;
- Defining data and informational needs (and review) for the topic area;
- Drafting the initial work plan with a timetable.

OWCP transcribes Advisory Board subcommittee meetings. OWCP posts the transcripts on the Advisory Board Web page, *http://www.dol.gov/owcp/energy/regs/compliance/AdvisoryBoard.htm,* along with written comments and other materials submitted to the subcommittee or presented at subcommittee meetings.

Public Participation, Submissions, and Access to the Public Record

Subcommittee meeting: The subcommittee will meet via teleconference on Monday, July 18, 2016, from 2:00 p.m. to 4:00 p.m. Eastern Time. Advisory Board subcommittee meetings are open to the public. The teleconference number and other details for listening to the meeting will be posted on the Advisory Board's Web site no later than 72 hours prior to the meeting. This information will be posted at *http://www.dol.gov/owcp/energy/regs/compliance/AdvisoryBoard.htm.*

Requests for special accommodations: Please submit requests for special accommodations to participate in the subcommittee meeting by email, telephone, or hard copy to Ms. Carrie Rhoads, OWCP, Room S–3524, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 343–5580; email *EnergyAdvisoryBoard@dol.gov.*

Submission of written comments for the record: You may submit written comments, identified by the subcommittee name and the meeting date of July 18, 2016, by any of the following methods:

- *Electronically:* Send to: *EnergyAdvisoryBoard@dol.gov* (specify in the email subject line, "Subcommittee on IH & CMC and Their Reports").
- *Mail, express delivery, hand delivery, messenger, or courier service:* Submit one copy to the following address: U.S. Department of Labor, Office of Workers' Compensation Programs, Advisory Board on Toxic Substances and Worker Health, Room S–3522, 200 Constitution Ave. NW., Washington, DC 20210. Due to security-related procedures, receipt of submissions by regular mail may experience significant delays.

Comments must be received by July 11, 2016. OWCP will make available publically, without change, any written comments, including any personal information that you provide. Therefore, OWCP cautions interested parties against submitting personal information such as Social Security numbers and birthdates.

Electronic copies of this **Federal Register** notice are available at *http://www.regulations.gov.* This notice, as well as news releases and other relevant information, are also available on the Advisory Board's Web page at *http://www.dol.gov/owcp/energy/regs/compliance/AdvisoryBoard.htm.*

FOR FURTHER INFORMATION CONTACT: You may contact Antonio Rios, Designated Federal Officer, at *rios.antonio@dol.gov,* or Carrie Rhoads, Alternate Designated Federal Officer, at *rhoads.carrie@dol.gov,* U.S. Department of Labor, 200 Constitution Avenue NW., Suite S–3524, Washington, DC 20210, telephone (202) 343–5580.

This is not a toll-free number.

Signed at Washington, DC, this 17th day of June, 2016.

Leonard J. Howie III,

Director, Office of Workers' Compensation Programs.

[FR Doc. 2016–14834 Filed 6–22–16; 8:45 am]

BILLING CODE 4510–24–P

LEGAL SERVICES CORPORATION

Sunshine Act Meeting; Notice

DATE AND TIME: The Legal Services Corporation's Finance Committee will meet telephonically on June 28, 2016. The meeting will commence at 3:00 p.m., EDT, and will continue until the conclusion of the Committee's agenda.

LOCATION: John N. Erlenborn Conference Room, Legal Services Corporation Headquarters, 3333 K Street NW., Washington, DC 20007.

PUBLIC OBSERVATION: Members of the public who are unable to attend in person but wish to listen to the public proceedings may do so by following the telephone call-in directions provided below.

CALL-IN DIRECTIONS FOR OPEN SESSIONS:

- Call toll-free number: 1–866–451–4981;
- When prompted, enter the following numeric pass code: 5907707348
- When connected to the call, please immediately "MUTE" your telephone.

Members of the public are asked to keep their telephones muted to eliminate background noises. To avoid disrupting the meeting, please refrain from placing the call on hold if doing so will trigger recorded music or other sound. From time to time, the Chair may solicit comments from the public.

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

1. Approval of agenda
2. Discussion with Management regarding recommendations for LSC's fiscal year 2018 budget request
    - Jim Sandman, President
    - Carol Bergman, Director, Government Relations and Public Affairs
3. Discussion with Inspector General regarding the OIG's fiscal year 2018 budget request
    - Jeffery Schanz, Inspector General
    - David Maddox, Assistant Inspector General for Management & Evaluation
4. Consider and act on FY 2018 Budget Request *Resolution 2016–XXX*
5. Public comment
6. Consider and act on other business
7. Consider and act on adjournment of meeting

CONTACT PERSON FOR INFORMATION: Katherine Ward, Executive Assistant to the Vice President & General Counsel, at (202) 295–1500. Questions may be sent by electronic mail to *FR_NOTICE_QUESTIONS@lsc.gov.*

ACCESSIBILITY: LSC complies with the Americans with Disabilities Act and Section 504 of the 1973 Rehabilitation Act. Upon request, meeting notices and materials will be made available in alternative formats to accommodate individuals with disabilities. Individuals needing other accommodations due to disability in order to attend the meeting in person or telephonically should contact Katherine Ward, at (202) 295–1500 or *FR_NOTICE_QUESTIONS@lsc.gov,* at least 2 business days in advance of the meeting. If a request is made without advance notice, LSC will make every effort to accommodate the request but cannot guarantee that all requests can be fulfilled.

Dated: June 21, 2016.

Katherine Ward,

Executive Assistant to the Vice President for Legal Affairs and General Counsel.

[FR Doc. 2016–15058 Filed 6–21–16; 4:15 pm]

BILLING CODE 7050–01–P

LEGAL SERVICES CORPORATION

Sunshine Act Meeting: Finance Committee, Postponed

AGENCY: Legal Services Corporation.

ACTION: Postponement notice.

SUMMARY: On June 16, 2016, the Legal Services Corporation (LSC) published a notice in the **Federal Register** (81 FR 39278) titled "Finance Committee Telephonic Meeting on June 22, 2016 at 3:30 p.m., EDT." The meeting has been postponed, and the agenda will be covered at a later date. This document announces the postponement of the meeting.

Changes in the Meeting: Postponed.

DATES: This postponement is effective June 21, 2016.

FOR FURTHER INFORMATION CONTACT: Katherine Ward, Executive Assistant to the Vice President for Legal Affairs and General Counsel, Legal Services Corporation, 3333 K Street NW., Washington, DC 20007; (202) 295–1500; *kward@lsc.gov.*

Dated: June 21, 2016.

Katherine Ward,

Executive Assistant to the Vice President for Legal Affairs and General Counsel.

[FR Doc. 2016–14979 Filed 6–21–16; 4:15 pm]

BILLING CODE 7050–01–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (16–044)]

NASA Advisory Council; Science Committee; Astrophysics Subcommittee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Astrophysics Subcommittee of the NASA Advisory Council (NAC). This Subcommittee reports to the Science Committee of the NAC. The meeting will be held for the purpose of soliciting, from the scientific community and other persons, scientific and technical information relevant to program planning.

DATES: Wednesday, July 20, 2016, 8:30 a.m.–4:00 p.m., and Thursday, July 21, 2016, 8:30 a.m.–4:00 p.m., Local Time.

ADDRESSES: NASA Headquarters, Room 3H42, 300 E Street SW., Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Ms. Ann Delo, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–0750, fax (202) 358–2779, or *ann.b.delo@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. This meeting will also be available telephonically and by WebEx. Any interested person may call the USA toll free conference call number 1–877–601–4492, passcode 7555144, or call the toll number 1–773–756–4808, passcode 7555144, both days. The WebEx link is *https://nasa.webex.com/;* the meeting number on July 20 is 991 261 734, password is Astrophysics!1; and the meeting number on July 21 is 999 492 706, password is Astrophysics!1.

The agenda for the meeting includes the following topics:

—Astrophysics Division Update

—Updates on Specific Astrophysics Mission

—Reports from the Program Analysis Groups

—Evaluation of Astrophysics Program as Required by Government Performance and Results Modernization Act

Attendees will be required to sign a register and comply with NASA Headquarters security requirements, including the presentation of a valid picture ID before receiving access to NASA Headquarters. Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID to Security before access to NASA Headquarters. Due to the Real ID Act, Public Law 109–13, any attendees with drivers licenses issued from non-compliant states/territories must present a second form of ID. [Federal employee badge; passport; active military identification card; enhanced driver's license; U.S. Coast Guard Merchant Mariner card; Native American tribal document; school identification accompanied by an item from LIST C (documents that establish employment authorization) from the "List of the Acceptable Documents" on Form I–9]. Non-compliant states/territories are: American Samoa, Illinois, Minnesota, Missouri, New Mexico and Washington. Foreign nationals attending this meeting will be required to provide a copy of their passport and visa in addition to providing the following information no less than 10 working days prior to the meeting: Full name; gender; date/place of birth; citizenship; visa information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee; and home address to Ms. Ann Delo via email at *ann.b.delo@nasa.gov* or by fax at (202) 358–2779. U.S. citizens and Permanent Residents (green card holders) are requested to submit their name and affiliation no less than 3 working days prior to the meeting to Ms. Ann Delo via email at *ann.b.delo@nasa.gov.* It is imperative that this meeting be held on these dates to accommodate the scheduling priorities of the key participants.

Patricia D. Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2016–14832 Filed 6–22–16; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL CREDIT UNION ADMINISTRATION

Submission for OMB Review; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice.

SUMMARY: The National Credit Union Administration (NCUA) will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before July 25, 2016 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for NCUA, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) NCUA PRA Clearance Officer, 1775 Duke Street, Alexandria, VA 22314–3428 or email at *PRAComments@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission may be obtained by emailing *PRAComments@ncua.gov* or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

OMB Number: 3133–0140.

Type of Review: Reinstatement, with change, of a previously approved collection.

Title: Secondary Capital for Low-Income Designated Credit Unions.

Abstract: Section 701.34 (b) of NCUA's regulations provide that designated low income credit unions (LICU) may accept secondary capital under certain conditions. This collection of information is necessary to obtain the information needed to ensure compliance with requirements related to acceptance and management of secondary capital. For those LICUs wishing to exercise their option to access secondary capital, NCUA requires that credit unions accepting secondary capital must develop and submit a plan for its acquisition, use and repayment. The information is used by NCUA to determine if the secondary capital will be managed by the credit union without risk to its financial condition, the U.S. government or the National Credit Union Share Insurance Fund.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 1,080.

By Gerard Poliquin, Secretary of the Board, the National Credit Union Administration, on June 20, 2016.

Dated: June 20, 2016.

Troy S. Hillier,

NCUA PRA Clearance Officer.

[FR Doc. 2016–14882 Filed 6–22–16; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Proposed Collection; Comment Request; Records Preservation

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice and request for comment.

SUMMARY: NCUA, as part of a continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on an extension of a currently approved collection, as required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

DATES: Written comments should be received on or before August 22, 2016 to be assured consideration.

ADDRESSES: Interested persons are invited to submit written comments on the information collection to Dawn Wolfgang, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314; Fax No. 703–519–8579; or Email at *PRAComments@NCUA.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to the address above.

SUPPLEMENTARY INFORMATION:

OMB Number: 3133–0032.

Title: Records Preservation, 12 CFR part 749.

Abstract: Part 749 requires all federally insured credit unions (FICUs) to maintain a records preservation program. The program must be in writing and include a schedule for the storage and destruction of records and emergency contact information for employees, officials, regulatory offices, and vendors used to support vital records. The collection of information is authorized by sections 120, 203, and 209 of the Federal Credit Union (FCU) Act; 12 U.S.C. 1766, 1783, and 1789.

The records preservation program requirement enables FICUs to reconstruct their vital records in the event records are destroyed by a catastrophe and facilitates restoration of vital member services.

Type of Review: Extension of a previously approved collection.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated No. of Respondents: 6,025.

Estimated No. of Responses per Respondent: 1.

Estimated Annual Responses: 6,025.

Estimated Burden Hours per Response: 2.

Estimated Total Annual Burden Hours: 12,074.

Adjustments are being made to the number of respondents due to a decline in the number of FICUs.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit comments concerning: (a) Whether the collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of the information on the respondents, including the use of automated collection techniques or other forms of information technology.

By Gerard Poliquin, Secretary of the Board, the National Credit Union Administration, on June 20, 2016.

Dated: June 20, 2016.

Dawn D. Wolfgang,

NCUA PRA Clearance Officer.

[FR Doc. 2016–14887 Filed 6–22–16; 8:45 am]

BILLING CODE 7535–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0252]

Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft NUREG; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is revising its licensing guidance for licenses authorizing distribution to general licensees. The NRC is requesting public comment on draft NUREG–1556, Volume 16, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance about Licenses Authorizing Distribution to General Licensees." The document has been updated from the previous revision to include information on safety culture, security of radioactive materials, protection of sensitive information, and changes in regulatory policies and practices. This document is intended for use by applicants, licensees, and the NRC staff.

DATES: Submit comments by July 25, 2016. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to assure consideration of comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0252. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H8, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Vanessa Cox, Office of Nuclear Material Safety and Safeguards; U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–8342; email: *Vanessa.Cox@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0252 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this action by the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0252.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737 or by email to *pdr.resource@nrc.gov.* The draft NUREG–1556, Volume 16, Revision 1, is available in ADAMS under Accession No. ML16167A386.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

The draft NUREG–1556, Volume 16, Revision 1, is also available on the NRC's public Web site on the: (1) "Consolidated Guidance About Materials Licenses (NUREG–1556)" page at *http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/;* and the (2) "Draft NUREG-Series Publications for Comment" page at *http://www.nrc.gov/public-involve/doc-comment.html#nuregs.*

B. Submitting Comments

Please include Docket ID NRC–2015–0252 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS, and the NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Further Information

The NUREG provides guidance to existing licensees that distribute generally licensed (GL) materials, products, or devices and to an applicant in preparing a license application to distribute GL materials, products, or devices. The NUREG also provides the NRC with criteria for evaluating a license application. The purpose of this notice is to provide the public with an opportunity to review and provide comments on draft NUREG–1556, Volume 16, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees." These comments will be considered in the final version or subsequent revisions.

Dated at Rockville, Maryland, this 17th day of June, 2016.

For the U.S. Nuclear Regulatory Commission.

Pamela J. Henderson,

Acting Director, Division of Material Safety, State, Tribal and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2016–14867 Filed 6–22–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Project No. PROJ0785; NRC–2016–0119]

Tennessee Valley Authority; Clinch River Nuclear Site

AGENCY: Nuclear Regulatory Commission.

ACTION: Early site permit application; receipt.

SUMMARY: On May 12, 2016, the Tennessee Valley Authority (TVA) filed with the U.S. Nuclear Regulatory Commission (NRC), an application for an early site permit (ESP) for the Clinch River Nuclear Site located in Oak Ridge, Tennessee.

DATES: The ESP application is available as of May 26, 2016.

ADDRESSES: Please refer to Docket ID NRC–2016–0119, when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0119. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents related to the application online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents,*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, the ADAMS accession numbers are provided in a table in the "Availability of Documents" section of this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Allen Fetter, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–8556, email: *Allen.Fetter@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

Pursuant to Section 103 of the Atomic Energy Act, as amended, and part 52 of title 10 of the *Code of Federal Regulations* (10 CFR), "Licenses, Certifications, and Approvals for Nuclear Power Plants," the applicant, TVA, filed an application with the NRC for an ESP in Oak Ridge, Tennessee. In accordance with dubpart A of 10 CFR part 52, an applicant may seek an ESP separate from the filing of an application for a construction permit (CP) or combined license (COL) for a nuclear power facility. The ESP process allows resolution of issues relating to siting. At any time during the period of an ESP (up to 20 years), the permit holder may reference the permit in an application for a CP or COL.

II. Further Information

The NRC will publish subsequent **Federal Register** notices addressing the acceptability of the tendered ESP application for docketing and provisions for public participation in the ESP application review process.

III. Availability of Documents

The following table indicates the ADAMS accession number or Web site where application documents are available to interested persons.

Document title	ADAMS accession No. or Web site
Application Transmittal letter for ESP for Clinch River Nuclear Site	ML16139A752.
Clinch River Nuclear Site Early Site Permit Application, Part 1, Administrative Information	ML16144A033.
Clinch River Nuclear Site Early Site Permit Application, Part 2, Site Safety Analysis Report	ML16144A074.
Clinch River Nuclear Site Early Site Permit Application, Part 3, Environmental Report	ML16144A145.
Clinch River Nuclear Site Early Site Permit Application, Part 5, Emergency Plan	ML16144A150.
Clinch River Nuclear Site Early Site Permit Application, Part 6, Exemptions and Departures	ML16144A151.
Early Site Permit Application—Clinch River Nuclear Site Web site	*http://www.nrc.gov/reactors/new-reactors/esp/clinch-river.html.*

The NRC will post publically available materials related to this application in ADAMS and on the NRC's public Web site at *http://www.nrc.gov/reactors/new-reactors/esp/clinch-river.html.*

Dated at Rockville, Maryland, this 17th day of June 2016.

For the Nuclear Regulatory Commission.

Francis M. Akstulewicz,

Director, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2016–14865 Filed 6–22–16; 8:45 am]

BILLING CODE 7590–01–P

PEACE CORPS

Information Collection Request; Submission for OMB Review

AGENCY: Peace Corps.

ACTION: 60-Day notice and request for comments.

SUMMARY: The Peace Corps will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval. The purpose of this notice is to allow 60 days for public comment in the **Federal Register** preceding submission to OMB. We are conducting this process in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

DATES: Submit comments on or before August 22, 2016.

ADDRESSES: Comments should be addressed to Denora Miller, FOIA/Privacy Act Officer. Denora Miller can be contacted by telephone at 202–692–1236 or email at *pcfr@peacecorps.gov.* Email comments must be made in text and not in attachments.

FOR FURTHER INFORMATION CONTACT: Denora Miller at Peace Corps address above.

SUPPLEMENTARY INFORMATION:

Title: Peace Corps Volunteer Application Form.

OMB Control Number: 0420–0005.

Type of Request: Revision.

Affected Public: Individuals.

Respondents Obligation To Reply: Voluntary.

Respondents: Potential Volunteers.

Burden to the Public:

a. Estimated number of respondents	23,000.
b. Estimated average burden per response	60 minutes.
c. Frequency of response	One Time.
d. Annual reporting burden	23,000 hours.

General description of collection: The information collected by the Volunteer Application is used by the Peace Corps to collect essential information from individual applicants, including technical and language skills, and availability for Peace Corps service. The information is used by the Peace Corps Office of VRS in its assessment of an individual's qualifications to serve as a Peace Corps Volunteer, including practical and cross-cultural experience, maturity, motivation and commitment. Selection for Peace Corps service is based on that assessment.

Request for Comment: Peace Corps invites comments on whether the proposed collections of information are necessary for proper performance of the functions of the Peace Corps, including whether the information will have practical use; the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the information to be collected; and, ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

This notice is issued in Washington, DC, on June 17, 2016.

Denora Miller,

FOIA/Privacy Act Officer, Management.

[FR Doc. 2016–14842 Filed 6–22–16; 8:45 am]

BILLING CODE 6051–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2016–215; MC2016–153 and CP2016–216; MC2016–154 and CP2016–217; MC2016–155 and CP2016–218; MC2016–156 and CP2016–219; CP2016–220; CP2016–221; CP2016–222]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 27, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov*. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's Web site (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.40.

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2016–215; *Filing Title:* Notice of the United States Postal Service of Filing a Functionally Equivalent Global Plus 1C Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal; *Filing Acceptance Date:* June 17, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*; *Public Representative:* Curtis E. Kidd; *Comments Due:* June 27, 2016.

2. *Docket No(s).:* MC2016–153 and CP2016–216; *Filing Title:* Request of the United States Postal Service to Add Priority Mail Contract 226 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* June 17, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*; *Public Representative:* Jennaca D. Upperman; *Comments Due:* June 27, 2016.

3. *Docket No(s).:* MC2016–154 and CP2016–217; *Filing Title:* Request of the United States Postal Service to Add First-Class Package Service Contract 56 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* June 17, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*; *Public Representative:* Katalin K. Clendenin; *Comments Due:* June 27, 2016.

4. *Docket No(s).:* MC2016–155 and CP2016–218; *Filing Title:* Request of the United States Postal Service to Add First-Class Package Service Contract 57 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* June 17, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*; *Public Representative:* Katalin K. Clendenin; *Comments Due:* June 27, 2016.

5. *Docket No(s).:* MC2016–156 and CP2016–219; *Filing Title:* Request of the United States Postal Service to Add Priority Mail Contract 227 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* June 17, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*; *Public Representative:* Jennaca D. Upperman; *Comments Due:* June 27, 2016.

6. *Docket No(s).:* CP2016–220; *Filing Title:* Notice of the United States Postal Service of Filing a Functionally Equivalent Global Plus 1C Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal; *Filing Acceptance Date:* June 17, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*; *Public Representative:* Curtis E. Kidd; *Comments Due:* June 27, 2016.

7. *Docket No(s).:* CP2016–221; *Filing Title:* Notice of the United States Postal Service of Filing a Functionally Equivalent Global Plus 3 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal; *Filing Acceptance Date:* June 17, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*; *Public Representative:* Kenneth R. Moeller; *Comments Due:* June 27, 2016.

8. *Docket No(s).:* CP2016–222; *Filing Title:* Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 3 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal; *Filing Acceptance Date:* June 17, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*; *Public Representative:* Kenneth R. Moeller; *Comments Due:* June 27, 2016.

This notice will be published in the **Federal Register**.

Stacy L. Ruble,
Secretary.

[FR Doc. 2016–14885 Filed 6–22–16; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2016–214]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 24, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's Web site (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.40.

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2016–214; *Filing Title:* Notice of the United States Postal Service of Filing a Functionally Equivalent Global Plus 1C Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal; *Filing Acceptance Date:* June 16, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Curtis E. Kidd; *Comments Due:* June 24, 2016.

This notice will be published in the **Federal Register**.

Stacy L. Ruble,
Secretary.

[FR Doc. 2016–14836 Filed 6–22–16; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78094; File No. SR–FINRA–2016–014]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Approving Proposed Rule Change Relating to Composition, Terms of Members and Election Procedures for the National Adjudicatory Council

June 17, 2016.

I. Introduction

On April 28, 2016, the Financial Industry Regulatory Authority, Inc. ("FINRA") filed with the Securities and Exchange Commission ("SEC" or "Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend the By-Laws of FINRA's regulatory subsidiary, FINRA Regulation, Inc. ("FINRA Regulation"), to expand the size of the National Adjudicatory Council ("NAC") to 15 members, with the number of non-industry members exceeding the number of industry members; lengthen the terms of office of future NAC members to four years; and update the process used for sending and counting ballots in the event of a contested nomination and election to fill certain NAC industry member seats. The proposed rule change was published for comment in the **Federal Register** on May 13, 2016.[3] The Commission received four comment letters on the proposal.[4] Thereafter, FINRA submitted a letter in response to the comment letters.[5] This order grants approval of the proposed rule change.

II. Description of the Proposal[6]

The FINRA Regulation By-Laws establish the composition of the NAC,[7] the terms of its members, and the process by which members are selected. The NAC is currently composed of fourteen members.[8] The number of Non-Industry Members, which must include at least three Public Members, equals the number of Industry Members.[9] The seven Industry Members include two Small Firm NAC Members, one Mid-Size Firm NAC Member, two Large Firm NAC Members and two at-large Industry Members.[10]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 77786 (May 9, 2016), 81 FR 29929 (May 13, 2016) ("Notice").

[4] *See* Letters from Steven B. Caruso, Esq., Maddox Hargett Caruso, P.C., dated May 9, 2016 ("Caruso Letter"); David T. Bellaire, Esq., Executive Vice President & General Counsel, Financial Services Institute, dated May 19, 2016 ("FSI Letter"); Hugh Berkson, Public Investors Arbitration Bar Association, dated June 2, 2016 ("PIABA Letter"); and Christopher E. Berman, Barry University, dated June 2, 2016 ("Berman Letter").

[5] *See* Letter from Gary Dernelle, Associate General Counsel, FINRA, dated June 13, 2016 ("FINRA Letter").

[6] A full description of the proposal can be found in the Notice. *See* Notice, *supra* note 3.

[7] The NAC acts on behalf of FINRA in several capacities and its powers are authorized by the By-Laws of FINRA Regulation and FINRA's Code of Procedure. The NAC presides over disciplinary matters appealed to or called for review by the NAC. The NAC also acts, when requested, in statutory disqualification and membership proceedings; considers the appeals of members seeking exemptive relief; and retains the authority to review decisions proposed in other proceedings as set forth in the Code of Procedure. For most matters that the NAC considers, it prepares a proposed written decision, which becomes final FINRA action if the Board does not call the matter for review. *See* Notice, *supra* note 3.

[8] *See* FINRA Regulation By-Laws, Article V (National Adjudicatory Council), Section 5.2(a) (Number of Members and Qualifications).

[9] *Id.* A "Non-Industry Member" of the NAC includes any Public Member, an officer or employee of an issuer of securities listed on a market for which FINRA provides regulation, an officer or employee of an issuer of unlisted securities that are traded in the over-the-counter market, or any individual who would not otherwise fall within the definition of an Industry Member. *See* FINRA Regulation By-Laws, Article I (Definitions), paragraph (ee). A "Public Member" generally is a Non-Industry Member who has no material business relationship with a broker or dealer or a self-regulatory organization registered under the Act. *See* FINRA Regulation By-Laws, Article I (Definitions), paragraph (hh). An "Industry Member" generally includes a person who is or served in the prior year as an officer, director, employee or controlling person of a broker-dealer; is an officer, director or employee of an entity that owns a material equity interest in a broker-dealer; owns personally a material equity interest in a broker-dealer; provides professional services to broker-dealers, or to a director, officer, or employee of a broker-dealer in their professional capacity, where the revenues from such services meet material thresholds; or is or served in the prior year as a consultant, employee or provider of

The FINRA Board appoints the NAC and its members.[11] The FINRA Board appoints Non-Industry Members and at-large Industry Members from candidates recommended by the Nominating Committee. The FINRA Board also appoints Small Firm, Mid-Size Firm and Large Firm NAC Members, either from candidates recommended by the Nominating Committee, or in the event of a contested election for a Small Firm, Mid-Size Firm or Large Firm NAC Member vacancy, the candidate who is elected by FINRA members based on their vote for a candidate.[12] The Small Firm, Mid-Size Firm or Large Firm NAC Member candidate receiving the largest number of votes from firms of corresponding size is declared the nominee, and the Nominating Committee sends a written certification of the results to the FINRA Board and nominates such candidate for appointment to the NAC.[13]

The proposed rule change amends the FINRA Regulation By-Laws in three ways. First, it amends Section 5.2 of the FINRA Regulation By-Laws to expand the size of the NAC from fourteen members to fifteen members and require that the NAC have more Non-Industry Members, including at least three Public Members, than Industry Members. Accordingly, FINRA would add one Non-Industry Member seat to the current 14-member committee.

Second, the proposed rule change lengthens the term of office of future NAC members by one year, from three to four years.[14] In addition, the NAC would be divided into four classes, rather than the current three, that are as equal in number as feasible.[15]

Finally, the proposed rule change streamlines the NAC election process and aligns it with the process currently used for elections involving the FINRA District Committees. The proposed rule change amends Section 6.7 of the FINRA Regulation By-Laws by deleting the term "envelope" and adding language to permit ballots to be delivered by additional means.[16] The proposed rule change aligns the ballot preparation process in NAC elections with that used in FINRA District Committee elections and allows FINRA members to vote using online and telephonic methods in addition to paper ballots.[17]

The proposed rule change also amends Section 6.10 of the FINRA Regulation By-Laws to simplify the tabulation of ballots by the Independent Agent, by eliminating the provision in Section 6.10 of the FINRA Regulation By-Laws that permits NAC candidates and their representatives to observe the Independent Agent's accounting of ballots in contested NAC elections. The proposed rule change would align the ballot counting process used in NAC elections with the process used in FINRA District Committee elections, which does not provide candidates the ability to be present while the Independent Agent opens and counts the ballots.[18] The proposed rule change will thus expedite the accounting process and permit the Secretary of FINRA to notify the candidates more quickly of NAC election results.

III. Summary of Comment Letters and FINRA's Response

One commenter supported the proposed rule change and believed that expanding the size of the NAC and requiring that the number of Non-Industry Members exceed the number of Industry Members would "clearly advance the public interest and protect investors. . . ."[19] Two commenters generally supported the proposed rule change, but believed that FINRA should increase the number of Public Members on the NAC instead of adding an additional Non-Industry Member to the NAC.[20] Finally, one commenter expressed concerns about modifying the composition of the NAC and lengthening the term of office of future NAC members.[21]

A. Composition of the NAC

Two commenters suggested that FINRA increase the number of Public Members on the NAC.[22] Specifically, one commenter expressed concern that while altering the NAC's composition to include a majority of Non-Industry Members would "enhance its reputation for impartiality and reduce the possibility of deadlock[,]"persons with significant industry connections may qualify as Non-Industry Members.[23] Similarly, another commenter believed that issuers and employees of issuers who would be categorized as Non-Industry Members "may be more closely aligned with Industry Members under certain circumstances." [24] One commenter, however, raised concerns about modifying the composition of the

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professional services to a self-regulatory organization registered under the Act. *See* FINRA Regulation By-Laws, Article I (Definitions), paragraph (x).

[10] *See* FINRA Regulation By-Laws, Article V (National Adjudicatory Council), Section 5.2(a) (Number of Members and Qualifications).

[11] *See* FINRA Regulation By-Laws, Article V (National Adjudicatory Council), Section 5.3 (Appointments).

[12] *Id.*

[13] *See* FINRA Regulation By-Laws, Article VI (Selection of Small Firm, Mid-Size Firm and Large Firm Industry Members of the National Adjudicatory Council), Section 6.13 (Certification of Nomination). The FINRA Board is required to appoint to the NAC the candidate who receives the most votes in any contested election for a Small Firm, Mid-Size Firm or Large Firm NAC Member seat. *See* FINRA Regulation By-Laws Article V (National Adjudicatory Council), Section 5.5 (Rejection of Nominating Committee Nominee).

[14] *See* Proposed FINRA Regulation By-Laws, Article V (National Adjudicatory Council), Section 5.6(a) and (c) (Term of Office). FINRA stated that the proposed rule change would not alter or extend the term of any NAC member serving currently; the rule change would apply prospectively.

[15] *See* Proposed FINRA Regulation By-Laws, Article V (National Adjudicatory Council), Section 5.6(b) (Term of Office). The proposed rule change also amends Section 5.6(a) of the FINRA Regulation By-Laws to provide a three-year transitional period during which the FINRA Board may appoint new NAC members to terms of office less than four years to achieve the staggering necessary to divide the NAC into four classes. FINRA anticipates that, beginning in January 2017, and ending in December 2019, new NAC members would be appointed to terms of either three years or four years to achieve the result of a NAC that is divided into four classes, with each NAC member serving a term of four years. The proposed rule change also makes a conforming amendment to Section 5.6(b) of the FINRA Regulation By-Laws to delete obsolete text related to a prior rule change that replaced region-based Industry NAC members with Industry members that represent FINRA member firms of various sizes. *See* Securities Exchange Act Release No. 58909 (November 6, 2008), 73 FR 68467 (November 18, 2008) (Order Approving File No. SR–FINRA–2008–046).

[16] The proposed rule change would also make a conforming amendment to Section 6.9 of the FINRA Regulation By-Laws concerning ballots that are returned as undelivered.

[17] *See* FINRA Regulation By-Laws, Article VIII (District Committees), Section 8.11 (Ballots).

[18] *See* FINRA Regulation By-Laws, Article VIII (District Committees), Section 8.14 (General Procedures for Qualification and Accounting of Ballots). According to FINRA, the opportunity to observe the Independent Agent's qualification and accounting of ballots was rarely used by NAC candidates and provided candidates no additional grounds for recourse. Candidates and their representatives are not allowed to see the vote of any FINRA member and the final determination of the qualification of a ballot rests with the Secretary of the Corporation. *See* FINRA Regulation By-Laws, Article VI (Selection of Small Firm, Mid-Size Firm and Large Firm Industry Members of the National Adjudicatory Council), Section 6.10 (General Procedures for Qualification and Accounting of Ballots). FINRA noted that the Secretary of the Corporation must still certify election results. *See* FINRA Regulation By-Laws, Article VI (Selection of Small Firm, Mid-Size Firm and Large Firm Industry Members of the National Adjudicatory Council), Section 6.13 (Certification of Nomination).

[19] *See* Caruso Letter (recommending that the proposed rule change be approved on an expedited basis).

[20] *See* Berman Letter and PIABA Letter.

[21] *See* FSI Letter.

[22] *See* Berman Letter and PIABA Letter.

[23] *See* Berman Letter.

[24] *See* PIABA Letter.

NAC.[25] This commenter believed that the current composition of the NAC achieves a more balanced perspective and that increasing the number of Non-Industry Members on the NAC could diminish expertise on the NAC.

In its response, FINRA noted that the current and proposed FINRA Regulation By-Laws do not limit the ability of the Board to appoint more than three Public Members to the NAC.[26] However, FINRA believed that explicitly increasing the number of Non-Industry Members that must also be Public Members would unnecessarily restrict FINRA's flexibility to appoint to the NAC a diversity of Non-Industry Members and Public Members that serve best, based on the pool of potential candidates, to strengthen the quality of the NAC and its deliberations and decisions. Further, with respect to concerns regarding Non-Industry Members aligning with Industry Members because of their connections to the securities industry, FINRA made clear that the term Non-Industry Member explicitly excludes any individual that would otherwise fall within the definition of an Industry Member[27] and that the proposed rule change is similar to the current FINRA By-Laws that require the number of public governors that serve on the Board to exceed the number of industry governors.[28]

In response to the commenter's concern that increasing the number of Non-Industry Members may diminish the NAC's balanced perspective and expertise, FINRA noted that the proposed rule change still maintains FINRA's custom of "substantial industry participation in the NAC's adjudication of disciplinary and other matters." Further, FINRA represented that it is committed to appointing Non-Industry Members that are both highly qualified and provide unique perspectives in NAC deliberations, including expertise in a variety of subjects and issues important to the matters the NAC considers, such as the federal securities laws, just and equitable principals of trade, best professional practices, and corporate governance and compliance.

B. Terms of Office for NAC Members

One commenter explicitly supported extending the terms of NAC members from three to four years.[29] This commenter believed that the annual turnover of NAC members compromised the NAC's effectiveness and that unseasoned members lacked the same institutional knowledge as members that have spent a more significant amount of time on the NAC.[30] However, another commenter raised concerns about extending terms on the NAC.[31] This commenter, while recognizing the benefit of extending member terms to four years, believed that the current three-year term allows for a rolling board with a variety of views. Accordingly, this commenter suggested that FINRA amend its proposal to re-evaluate the proposed four-year term at a future date.

In its response, FINRA noted that the proposed rule change would maintain the current NAC member term limit, which generally prohibits NAC members from serving consecutive terms, and staggered terms. According to FINRA, this should allow a "regular infusion of fresh ideas and knowledge and generally serve the goal of invigorating NAC deliberations" with the composition of the NAC changing each year, while allowing NAC members to be fully productive for a longer term. Further, with respect to the commenter's suggestion to re-evaluate the four-year term at a future date, FINRA noted that the NAC's decisions are generally subject to discretionary review by the FINRA Board of Governors. As a result, the FINRA Board of Governors is "well placed to conduct an ongoing evaluation of the NAC's effectiveness and the quality of its decision making" and therefore, amending the proposed rule change to establish a date for reevaluating the effectiveness of the longer member terms is unnecessary.

C. NAC Selection Process

One commenter believed that the revised selection process for contested elections would make the process more efficient and allow for electronic balloting.[32]

IV. Discussion and Commission Findings

After carefully considering the proposal, the comments submitted, and FINRA's response, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities association.[33] Specifically, the Commission finds that the proposed rule change is consistent with Sections 15A(b)(4), 15A(b)(6) and 15A(b)(8) of the Act,[34] which require, among other things, that FINRA rules assure a fair representation of its members in the administration of its affairs; are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest; and provide a fair procedure for disciplining of members and persons associated with members.

The Commission believes that FINRA's proposal to add one Non-Industry Member to the NAC should enhance the independence of the NAC and continue to ensure that a diversity of expertise, experiences and views are represented on the NAC. With respect to commenters' suggestion that FINRA should increase the number of Public Members on the NAC,[35] the Commission notes that under the proposed rule change FINRA still may appoint more than three Public Members to the NAC,[36] but retains flexibility to appoint an additional Non-Industry Member or Public Member. According to FINRA, requiring that the Non-Industry Member be a Public Member would restrict its ability to appoint members that serve best, "based on the pool of potential candidates, to strengthen the quality of the NAC as an adjudicatory body and its deliberations and decisions."[37] Further, with respect to concerns that the current composition of the NAC provides a more balanced perspective and expertise,[38] FINRA has represented that it will continue to appoint Non-Industry Members that are both highly qualified and provide unique perspectives and expertise in NAC deliberations.[39] Moreover, while Non-Industry Members would exceed the number of Industry Members, seven of the fifteen NAC members would continue to be Industry Members, including two Small Firm NAC Members, one Mid-Size Firm NAC Member, two Large Firm NAC Members, and two at-large Industry Members.[40] Accordingly, the Commission believes that the proposed rule change continues to allow for substantial industry participation, while enhancing the overall independence of the NAC.

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[25] *See* FSI Letter.

[26] *See* FINRA Letter.

[27] *See* FINRA Letter (citing to FINRA Regulation By-Laws, Article I (Definitions), paragraph (ee) (defining Non-Industry Member)).

[28] According to FINRA, while the terms Non-Industry Member and Public Governor are not identical, they are comparable. *See* FINRA Letter.

[29] *See* Berman Letter.

[30] *See* Berman Letter.

[31] *See* FSI Letter.

[32] *See* Berman Letter.

[33] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[34] 15 U.S.C. 78*o*-3(b)(4), (b)(6) and (b)(8).

[35] *See* Berman Letter and PIABA Letter.

[36] *See* current and proposed FINRA Regulation By-Laws, Article V (National Adjudicatory Council), Section 5.2(a) (Number of Members and Qualifications) (stating that the National Adjudicatory Council shall consist of at least three Public Members).

[37] *See* FINRA Letter.

[38] *See* FSI Letter.

[39] *See* FINRA Letter. In the past, Non-Industry Members have included professors of law, finance, and business; current and former public pension and retirement system advisers; and leaders of independent, non-profit organizations that provide educational and outreach programs to issuers and investors. *Id.*

The Commission also believes it is appropriate for FINRA to increase the term of NAC members from three to four years. While one commenter raised concerns about extending member terms,[41] the Commission believes that the proposed rule change will allow NAC members to spend more time serving and being fully productive after gaining experience on the NAC. At the same time, the Commission believes the current term limits, staggered terms, and composition of the NAC should continue to provide the NAC with varied perspectives and views.

The Commission also believes that the proposed changes to the NAC selection process to modernize and streamline the process and to align it with the process used in FINRA District Committee elections are appropriate.[42] The proposed rule change would allow ballots to be delivered and voted by means other than the mail and further simplify the tabulation process by eliminating the provision that allowed NAC candidates and their representatives to observe the Independent Agent's accounting of ballots in a contested election. FINRA stated that candidates rarely opted to observe the Independent Agent and observing the Independent Agent did not provide candidates additional grounds for recourse. NAC candidates and their representatives were not allowed to see the vote of any FINRA member and the final determination of the qualification of a ballot rested with the Secretary of FINRA.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[43] that the proposed rule change (FINRA–2016–014) be, and it hereby is approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[44]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–14837 Filed 6–22–16; 8:45 am]

BILLING CODE 8011–01–P

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[40] *See* current and proposed FINRA Regulation By-Laws, Article V (National Adjudicatory Council), Section 5.2(a) (Number of Members and Qualifications).

[41] *See* FSI Letter.

[42] *See* FINRA Regulation By-Laws, Article VIII (District Committees), Sections 8.11 (Ballots), 8.13 (Ballots Returned as Undelivered), and 8.14 (General Procedures for Qualification and Accounting of Ballots).

[43] 15 U.S.C. 78s(b)(2).

[44] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:

Rule 19b–4 and Form 19b–4, SEC File No. 270–38, OMB Control No. 3235–0045.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 ("PRA") (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") is soliciting comments on the existing collection of information provided for in Rule 19b–4 (17 CFR 240.19b–4), under the Securities Exchange Act of 1934 ("Act") (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget ("OMB") for extension and approval.

Section 19(b) of the Act (15 U.S.C. 78s(b)) requires each self-regulatory organization ("SRO") to file with the Commission copies of any proposed rule, or any proposed change in, addition to, or deletion from the rules of such SRO. Rule 19b–4 implements the requirements of Section 19(b) by requiring the SROs to file their proposed rule changes on Form 19b–4 and by clarifying which actions taken by SROs are subject to the filing requirement set forth in Section 19(b). Rule 19b–4(n) requires a designated clearing agency to provide the Commission advance notice ("Advance Notice") of any proposed change to its rules, procedures, or operations that could materially affect the nature or level of risks presented by such clearing agency. Rule 19b–4(o) requires a registered clearing agency to submit for a Commission determination any security-based swap, or any group, category, type, or class of security-based swaps it plans to accept for clearing ("Security-Based Swap Submission"), and provide notice to its members of such submissions.

The collection of information is designed to provide the Commission with the information necessary to determine, as required by the Act, whether the proposed rule change is consistent with the Act and the rules thereunder. The information is used to determine if the proposed rule change should be approved, disapproved, suspended, or if proceedings should be instituted to determine whether to approve or disapprove the proposed rule change.

The respondents to the collection of information are SROs (as defined by Section 3(a)(26) of the Act),[1] including national securities exchanges, national securities associations, registered clearing agencies, notice registered securities future product exchanges, and the Municipal Securities Rulemaking Board.

In calendar year 2015, each respondent filed an average of approximately 57 proposed rule changes. Each filing takes approximately 39 hours to complete on average. Thus, the total annual reporting burden for filing proposed rule changes with the Commission is 86,697 hours (57 proposals per year × 39 SROs × 39 hours per filing) for the estimated future number of 39 SROs.[2] In addition to filing their proposed rule changes with the Commission, the respondents also are required to post each of their proposals on their respective Web sites, a process that takes approximately four hours to complete per proposal. Thus, for 1,935 proposals, the total annual reporting burden on respondents to post the proposals on their Web sites is 7,740 hours (1,935 proposals per year × 4 hours per filing) or 8,892 hours (57 proposals per year × 39 SROs × 4 hours per filing) for the estimated future number of 39 SROs. Further, the respondents are required to update their rulebooks, which they maintain on their Web sites, to reflect the changes that they make in each proposal they file. Thus, for all filings that were not withdrawn by a respondent (240 withdrawn filings in calendar year 2015) or disapproved by the Commission (6 disapproved filings in calendar year 2015), the respondents were required to update their online rulebooks to reflect the effectiveness of 1,689 proposals, each of which takes approximately four hours to complete per proposal. Thus, the total annual reporting burden for updating online rulebooks is 7,764 hours ((2,223 filings per year − 275 withdrawn filings[3] − 7 disapproved filings[4]) × 4 hours). Finally, a respondent is required to notify the Commission if it does not post a proposed rule change on its Web site on the same day that it filed the proposal with the Commission. The Commission estimates that SROs will fail to post proposed rule changes on their Web sites on the same day as the filing 22 times a year (across all SROs), and that each SRO will spend approximately one hour preparing and submitting such notice to the Commission, resulting in a total annual burden of 22 hours (22 notices × 1 hour per notice).

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[1] 15 U.S.C. 78c(a)(26).

[2] For most of 2015, 34 SROs were registered. One registered SRO withdrew in December 2015 and one SRO newly registered with the Commission in January 2016. The Commission expects five additional respondents to register during the three-year period for which this PRA Extension is applicable (three as registered clearing agencies and two as national securities exchanges), bringing the total number of respondents to 39.

Designated clearing agencies have additional information collection burdens. As noted above, pursuant to Rule 19b–4(n), a designated clearing agency must file with the Commission an Advance Notice of any proposed change to its rules, procedures, or operations that could materially affect the nature or level of risks presented by such designated clearing agency. The Commission estimates that four designated clearing agencies will each submit five Advance Notices per year, with each submission taking 90 hours to complete. The total annual reporting burden for filing Advance Notices is therefore 1,800 hours (4 designated clearing agencies × 5 Advance Notices per year × 90 hours per response).

Designated clearing agencies are required to post all Advance Notices to their Web sites, each of which takes approximately four hours to complete. For five Advance Notices, the total annual reporting burden for posting them to respondents' Web sites is 80 hours (4 designated clearing agencies × 5 Advance Notices per year × 4 hours per Web site posting). Respondents are required to update the postings of those Advance Notices that become effective, each of which takes approximately four hours to complete. The total annual reporting burden for updating Advance Notices on the respondents' Web sites is 80 hours (4 designated clearing agencies × 5 Advance Notices per year × 4 hours per Web site posting).

Pursuant to Rule 19b–4(n)(5), the respondents are also required to provide copies of all materials submitted to the Commission relating to an Advance Notice to the Board of Governors of the Federal Reserve System ("Board") contemporaneously with such submission to the Commission, which is estimated to take two hours. The total annual reporting burden for designated clearing agencies to meet this requirement is 40 hours (4 designated clearing agencies × 5 Advance Notices per year × 2 hours per response).

The Commission estimates that three security-based swap clearing agencies will each submit 20 Security-Based Swap Submissions per year, with each submission taking 140 hours to complete resulting in a total annual reporting burden of 8,400 hours (3 respondent clearing agencies × 20 Security-Based Swap Submissions per year × 140 hours per response). Respondent clearing agencies are required to post all Security-Based Swap Submissions to their Web sites, each of which takes approximately four hours to complete. For 20 Security-Based Swap Submissions, the total annual reporting burden for posting them to the three respondents' Web sites is 240 hours (3 respondent clearing agencies × 20 Security-Based Swap Submissions per year × 4 hours per Web site posting). In addition, three clearing agencies that have not previously posted Security-Based Swap Submissions, Advance Notices, and proposed rule changes on their Web sites may need to update their existing Web sites to post such filings online. The Commission estimates that each of these three clearing agencies would spend approximately 15 hours updating its existing Web site, resulting in a total one-time burden of 45 hours (3 respondent clearing agencies × 15 hours per Web site update) or 15 hours annualized over three years.

Respondent clearing agencies will also have to provide training to staff members using the Electronic Form 19b–4 Filing System ("EFFS") to submit Security-Based Swap Submissions, Advance Notices, and/or proposed rule changes electronically. The Commission estimates that one anticipated security-based swap clearing agency will spend approximately 20 hours training all staff members who will use EFFS to submit Security-Based Swap Submissions, Advance Notices, and/or proposed rule changes electronically, or 6.7 hours annualized over three years. The Commission also estimates that one anticipated clearing agency will have a one-time burden of 130 hours to draft and implement internal policies and procedures for using EFFS to make these submissions, or 43.3 hours annualized over three years. The Commission estimates that each of the 39 respondents will spend 10 hours each year training new compliance staff members and updating the training of existing compliance staff members to use EFFS, for a total annual burden of 390 hours (39 respondent SROs × 10 hours).

In connection with Security-Based Swap Submissions, counterparties may apply for a stay from a mandatory clearing requirement under Rule 3Ca–1. The Commission estimates that each clearing agency will submit five applications for stays from a clearing requirement per year and it will take approximately 18 hours to retrieve, review, and submit each application. Thus, the total annual reporting burden for the Rule 3Ca–1 stay of clearing requirement would be 270 hours (3 respondent clearing agencies × 5 stay of clearing applications per year × 18 hours to retrieve, review, and submit the stay of clearing information).

Based on the above, the total estimated annual response burden pursuant to Rule 19b–4 and Form 19b–4 is the sum of the total annual reporting burdens for filing proposed rule changes, Advance Notices, and Security-Based Swap Submissions; training staff to file such proposals; drafting, modifying, and implementing internal policies and procedures for filing such proposals; posting each proposal on the respondents' Web sites; updating Web sites to enable posting of proposals; updating the respondents' online rulebooks to reflect the proposals that became effective; submitting copies of Advance Notices to the Board; and applying for stays from clearing requirements, which is 114,740 hours.

Compliance with Rule 19b–4 is mandatory. Information received in response to Rule 19b–4 shall not be kept confidential; the information collected is public information.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

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[3] For 34 SROs, 240 withdrawn filings equal approximately 7.06 filings per SRO. For 39 SROs, the figure would increase to 275 withdrawn filings.

[4] For 34 SROs, six disapproved filings equal approximately 0.18 filings per SRO. For 39 SROs, the figure would increase to seven disapproved filings.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or by sending an email to *PRA_Mailbox@sec.gov.*

Dated: June 17, 2016.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–14840 Filed 6–22–16; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice: 9614]

Notification of the Next CAFTA–DR Environmental Affairs Council Meeting

AGENCY: Department of State.

ACTION: Notice of the CAFTA–DR Environmental Affairs Council Meeting and request for comments.

SUMMARY: The Department of State and the Office of the United States Trade Representative are providing notice that the parties to the Dominican Republic-Central America-United States Free Trade Agreement (CAFTA–DR) intend to hold the tenth meeting of the Environmental Affairs Council (the Council) established under Chapter 17 (Environment) of that agreement in San Salvador, El Salvador, on July 7 and 8, 2016. The Council will commemorate the tenth anniversary of CAFTA–DR by highlighting the many environmental accomplishments of the past ten years and charting a course for the future. On July 7, the Council will meet to review implementation of Chapter 17 of CAFTA–DR and the CAFTA–DR Environmental Cooperation Agreement (ECA). All interested persons are invited to attend the Council's public session beginning at 9:00 a.m. on July 8 at the Hotel Sheraton Presidente in San Salvador.

During the July 7 Council meeting, Council members will present the progress made and challenges in implementing Chapter 17 obligations as well as the outcomes achieved through environmental cooperation in their respective countries. The Council will also receive a presentation from the CAFTA–DR Secretariat for Environmental Matters (SEM). More information on the Council is included below under **SUPPLEMENTARY INFORMATION.**

All interested persons are invited to attend the July 8 public session where they will have an opportunity to ask questions and discuss implementation of Chapter 17 and the Environmental Cooperation Agreement with Council Members. At the public session, the Council hopes to receive input from the public on current environmental challenges and ideas for future cooperation. The session will also offer the opportunity to hear directly from beneficiaries of the CAFTA–DR Environmental Cooperation Program and explore environmental progress in CAFTA–DR countries through a number of side events and interactive presentations. If you would like to attend the public session, please notify Neal Morris and Laura Buffo at the email addresses listed under the heading **ADDRESSES.** Please include your full name and identify any organization or group you represent.

The Department of State and Office of the United States Trade Representative also invite written comments or suggestions to be submitted before July 1, 2016 regarding topics to be discussed at the Council meeting. In preparing comments, we encourage submitters to refer to Chapter 17 of the CAFTA–DR, the Final Environmental Review of the CAFTA–DR, and the CAFTA–DR Environmental Cooperation Agreement (ECA) *(documents available at http://www.state.gov/e/oes/eqt/trade/caftadr/index.htm).* Instructions on how to submit comments are under the heading **ADDRESSES.**

DATES: The public session of the Council will be held on July 8, 2016, from 9:00 a.m.–4:00 p.m. at the Hotel Sheraton Presidente in San Salvador, El Salvador. We request comments and suggestions in writing no later than July 1, 2016.

ADDRESSES: Written comments or suggestions should be submitted to both:

(1) Neal Morris, U.S. Department of State, Bureau of Oceans and International Environmental and Scientific Affairs, Office of Environmental Quality and Transboundary Issues by email to *MorrisND@state.gov* with the subject line "CAFTA–DR EAC Meeting" or by fax to (202) 647–5947; and

(2) Laura Buffo, Director for Environment and Natural Resources, Office of the United States Trade Representative by email to *Laura_Buffo@ustr.eop.gov* with the subject line "CAFTA–DR EAC Meeting" or by fax to (202) 395–9517.

If you have access to the Internet you can view and comment on this notice by going to: *http://www.regulations.gov/#!home* and searching for docket number DOS–2016–0045.

FOR FURTHER INFORMATION CONTACT: Neal Morris, (202) 647–9312, or Laura Buffo, (202) 395–9424

SUPPLEMENTARY INFORMATION: Article 17.5 of the CAFTA–DR establishes an Environmental Affairs Council (the Council) and, unless the CAFTA–DR parties otherwise agree, requires it to meet annually to oversee the implementation of, and review progress under, Chapter 17. Article 17.5 further requires, unless the parties otherwise agree, that each meeting of the Council include a session in which members of the Council have an opportunity to meet with the public to discuss matters relating to the implementation of Chapter 17.

In Article 17.9, the parties recognize the importance of strengthening capacity to protect the environment and to promote sustainable development in concert with strengthening trade and investment relations and state their commitment to expanding their cooperative relationship on environmental matters. Article 17.9 also references the ECA, which sets out certain priority areas of cooperation on environmental activities. These priority areas include, among others: Reinforcing institutional and legal frameworks and the capacity to develop, implement, administer, and enforce environmental laws, regulations, standards and policies; conserving and managing shared, migratory and endangered species in international commercial trade and management of protected areas; promoting best practices leading to sustainable management of the environment; and facilitating technology development and transfer and training to promote clean production technologies. In preparing comments, we encourage submitters to refer to:

- Chapter 17 of the CAFTA–DR,
- The Final Environmental Review of CAFTA–DR, and
- The ECA.

These documents are available at: *http://www.state.gov/e/oes/eqt/trade/caftadr/index.htm.* Visit *http://www.state.gov* and the USTR Web site at *www.ustr.gov* for more information.

Dated: June 17, 2016.

Robert Wing,

Acting Director, Office of Environmental Quality and Transboundary Issues, U.S. Department of State.

[FR Doc. 2016–14927 Filed 6–22–16; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Request To Release Airport Property at the Monroe Regional Airport at Monroe, Louisiana

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Request to Release Airport Property.

SUMMARY: The FAA proposes to rule and invite public comment on the release of land at the Monroe Regional Airport at Monroe, Louisiana under the provisions of Section 125 of the Wendell H. Ford Aviation Investment Reform Act for the 21st Century (AIR 21).

DATES: Comments must be received on or before July 22, 2016.

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address: Mr. Lacey Spriggs, Manager, Federal Aviation Administration, Southwest Region, Airports Division, Louisiana/New Mexico Airports District Office, ASW–640, 10101 Hillwood Parkway, Fort Worth, Texas 76177.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to the Mr. Ron Phillips, Airport Manager, at the following address: 5400 Operations Road, Monroe, Louisiana 71203.

FOR FURTHER INFORMATION CONTACT: Mr. Bill Bell, Lead Engineer, Federal Aviation Administration, Louisiana/New Mexico Airports District Office, ASW–640, 10101 Hillwood Parkway, Fort Worth, Texas 76177, Telephone: (817) 222–5664, email: *Bill.Bell@faa.gov,* fax: (817) 222–5987.

The request to release property may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to release property at the Monroe Regional Airport at Monroe, Louisiana under the provisions of the AIR 21.

The following is a brief overview of the request:

The City of Monroe, Louisiana requests the release of 2.2 acres of non-aeronautical airport property. The land was acquired by Deed from the United States dated September 8, 1949. The property to be released will be sold and the funds will be used for the Airport's Bermuda Release program and purchase of a new tractor.

Any person may inspect the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT.**

In addition, any person may, upon request, inspect the application, notice and other documents relevant to the application in person at the Monroe Airport, Monroe, Louisiana, telephone number (318) 329–2460.

Ignacio Flores,

Manager, Airports Division.

[FR Doc. 2016–14635 Filed 6–22–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA 2016–0002–N–16]

Proposed Agency Information Collection Activity; Comment Request

AGENCY: Federal Railroad Administration (FRA), U.S. Department of Transportation.

ACTION: Notice and request for comments.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, FRA is informing the public it has revised the Annual Positive Train Control (PTC) Progress Report Form (Form FRA F 6180.166), which the Office of Management and Budget (OMB) previously approved on March 16, 2016, for a period of 180 days, under its emergency processing procedures. FRA revised the Annual PTC Progress Report Form based on comments it received from industry stakeholders on a related information collection, the Quarterly PTC Progress Report Form (Form FRA F 6180.165). Before submitting this annual information collection request to OMB for regular clearance, FRA is soliciting public comment on specific aspects of the proposed information collection identified below.

DATES: Comments must be received no later than August 22, 2016.

ADDRESSES: Submit written comments on the following proposed activity by mail to either: Mr. Robert Brogan, Office of Safety, Planning and Evaluation Division, RRS–21, Federal Railroad Administration, 1200 New Jersey Ave. SE., Mail Stop 17, Washington, DC 20590, or Ms. Kimberly Toone, Office of Information Technology, RAD–20, Federal Railroad Administration, 1200 New Jersey Ave. SE., Mail Stop 35, Washington, DC 20590. Commenters requesting FRA to acknowledge receipt of their respective comments must include a self-addressed stamped postcard stating, "Comments on OMB control number 2130–0553." Alternatively, comments may be transmitted via facsimile to (202) 493–6216 or (202) 493–6497, or via email to Mr. Brogan at *Robert.Brogan@dot.gov,* or to Ms. Toone at *Kim.Toone@dot.gov.* When submitting comments to FRA in response to this notice, please refer to the assigned OMB control number 2130–0553 and to Docket Number FRA–2016–0002–0016. FRA will summarize comments received in response to this notice in a subsequent notice and include the comments in its information collection submission to OMB for approval.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Brogan, Office of Planning and Evaluation Division, RRS–21, Federal Railroad Administration, 1200 New Jersey Ave. SE., Mail Stop 17, Washington, DC 20590 (telephone: (202) 493–6292) or Ms. Kimberly Toone, Office of Information Technology, RAD–20, Federal Railroad Administration, 1200 New Jersey Ave. SE., Mail Stop 35, Washington, DC 20590 (telephone: (202) 493–6132). (These telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION:

I. Public Comment Under the PRA

The PRA and its implementing regulations require Federal agencies to provide 60-days' notice to the public for comment on information collection activities before seeking approval for reinstatement or renewal by OMB. *See* 44 U.S.C. 3506(c)(2)(A) (1995); 5 CFR 1320.8(d)(1), 1320.10(e)(1), 1320.12(a). Specifically, FRA invites interested respondents to comment on: (i) Whether the information collection activity is necessary for FRA to properly execute its functions, including whether the activity will have practical utility; (ii) the accuracy of FRA's estimates of the burden of the information collection activity, including the validity of the methodology and assumptions used to determine the estimates; (iii) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (iv) ways for FRA to minimize the burden of the information collection activity on the public by automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submission of responses). *See* 44 U.S.C. 3506(c)(2)(A)(i)–(iv); 5 CFR 1320.8(d)(1)(i)–(iv). FRA believes soliciting public comment will promote its efforts to reduce the administrative and paperwork burdens associated with the collection of information. In summary, FRA reasons that comments received will advance three objectives: (i) Reduce reporting burdens; (ii) ensure that it organizes information collection requirements in a "user friendly" format to improve the use of such information; and (iii) accurately assess the resources expended to retrieve and produce information requested. *See* 44 U.S.C. 3501.

II. Background on the Annual PTC Reporting Requirement

Under the Positive Train Control Enforcement and Implementation Act of 2015 (PTCEI Act), each railroad subject to 49 U.S.C. 20157(a) must submit an annual progress report to FRA by March 31, 2016, and annually thereafter, until PTC implementation is completed. 49 U.S.C. 20157(c)(1). The PTCEI Act specifically requires each railroad to provide certain information in the annual reports regarding its progress toward implementing a PTC system, and authorizes FRA to request that railroads provide additional information in the annual progress reports. *See id.* In addition, 49 U.S.C. 20157(c)(2) requires FRA to conduct compliance reviews at least annually to ensure each railroad is complying with its revised PTC implementation plan (PTCIP). The PTCEI Act requires railroads to provide information to FRA that FRA determines is necessary to adequately conduct such compliance reviews. *See* 49 U.S.C. 20157(c)(2).

On March 16, 2016, OMB approved the Annual PTC Progress Report Form (Form FRA F 6180.166). However, based on industry's oral and written comments on the proposed Quarterly PTC Progress Report Form (Form FRA F 6180.165), FRA has revised the Annual PTC Progress Report Form to be as consistent with the quarterly report form as possible (where the questions overlap), thereby enabling railroads to transfer information from the quarterly report forms to the annual report forms more easily. In summary, on April 12, 2016, the Association of American Railroads (AAR) submitted comments to FRA on behalf of itself and its member railroads, and the American Public Transit Association (APTA) submitted comments to FRA on behalf of Metra, the Utah Transit Authority, the Tri-County Metropolitan Transportation District of Oregon, and the Fort Worth Transportation Authority.

On April 19, 2016, FRA held a meeting on the proposed Quarterly PTC Progress Report Form to offer the affected regulated entities a forum to provide additional comments and feedback to FRA. Representatives from, and members of, AAR, APTA, the American Short Line and Regional Railroad Association (ASLRRA), and some individual railroad representatives attended the meeting and provided feedback. FRA published minutes from the meeting on *www.regulations.gov* under Docket No. FRA–2016–0002. For a detailed summary of the oral and written comments and FRA's responses to the comments, please see 81 FR 28140 (May 9, 2016).

The current Annual PTC Progress Report Form, as approved through September 30, 2016, can be accessed and downloaded in FRA's eLibrary at: *https://www.fra.dot.gov/eLib/details/L17366.* To view the revised Annual PTC Progress Report Form that FRA hereby offers for public comment, please see the form attached to this **Federal Register** notice.

III. Overview of Information Collection

The associated collection of information is summarized below. FRA will submit this information collection request to OMB for regular clearance as required by the PRA.

Title: Annual Positive Train Control Progress Report.

OMB Control Number: 2130–0553.

Form Number(s): FRA F 6180.166.

Affected Public: Businesses.

Frequency of Submission: One-time; on occasion.

Respondent Universe: 41 Railroad Carriers.

Reporting Burden:

Annual PTC progress report	Respondent universe	Total annual responses	Average time per response (hours)	Total annual burden hours
Form FRA F 6180.166	41 Railroads	41 Reports/Forms	38.41	1,575

FRA notes that the 38.41-hour estimate is an average for all railroads. FRA estimated the annual reporting burden is 60 hours for Class I and large passenger railroads, 40 hours for Class II and medium passenger railroads, and 25 hours for Class III, terminal and small passenger railroads.

Total Estimated Annual Responses for Form FRA F 6180.166: 41.

Total Estimated Annual Burden for Form FRA F 6180.166: 1,575 hours.

Total Estimated Annual Responses for Entire Information Collection: 147,612.

Total Estimated Annual Burden for Entire Information Collection: 3,122,559.

Status: Regular Review.

Under 44 U.S.C. 3507(a) and 5 CFR 1320.5(b) and 1320.8(b)(3)(vi), FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

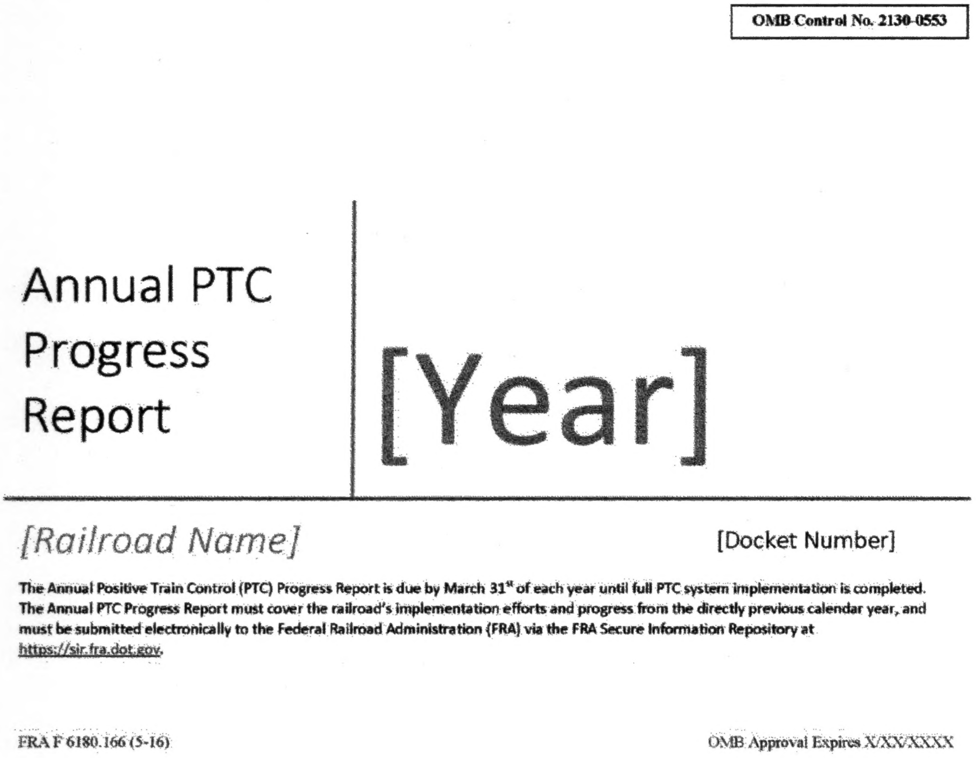
Authority: 44 U.S.C. 3501–3520.

Issued in Washington, DC, on June 20, 2016.

Corey Hill,

Executive Director.

BILLING CODE 4910–06–P



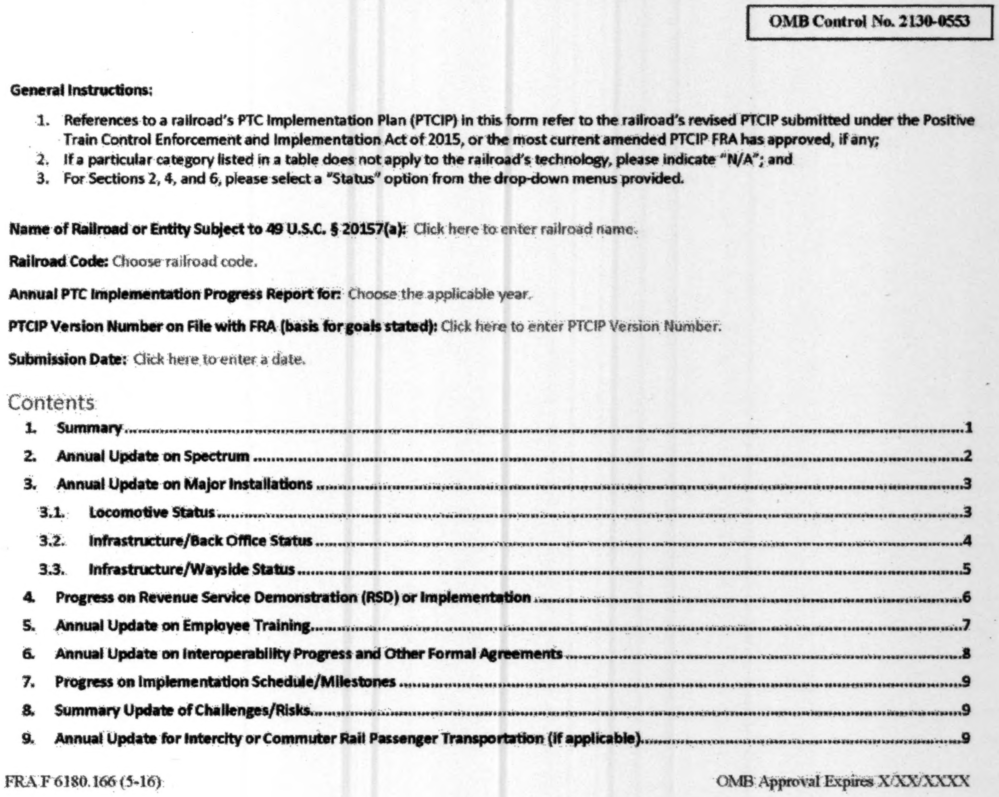
OMB Control No. 2130-0553

Annual PTC Progress Report [Year]

[Railroad Name] [Docket Number]

The Annual Positive Train Control (PTC) Progress Report is due by March 31st of each year until full PTC system implementation is completed. The Annual PTC Progress Report must cover the railroad's implementation efforts and progress from the directly previous calendar year, and must be submitted electronically to the Federal Railroad Administration (FRA) via the FRA Secure Information Repository at https://sir.fra.dot.gov.

FRA F 6180.166 (5-16) OMB Approval Expires X/XX/XXXX



OMB Control No. 2130-0553

General Instructions:

1. References to a railroad's PTC Implementation Plan (PTCIP) in this form refer to the railroad's revised PTCIP submitted under the Positive Train Control Enforcement and Implementation Act of 2015, or the most current amended PTCIP FRA has approved, if any;
2. If a particular category listed in a table does not apply to the railroad's technology, please indicate "N/A"; and
3. For Sections 2, 4, and 6, please select a "Status" option from the drop-down menus provided.

Name of Railroad or Entity Subject to 49 U.S.C. § 20157(a): Click here to enter railroad name.

Railroad Code: Choose railroad code.

Annual PTC Implementation Progress Report for: Choose the applicable year.

PTCIP Version Number on File with FRA (basis for goals stated): Click here to enter PTCIP Version Number.

Submission Date: Click here to enter a date.

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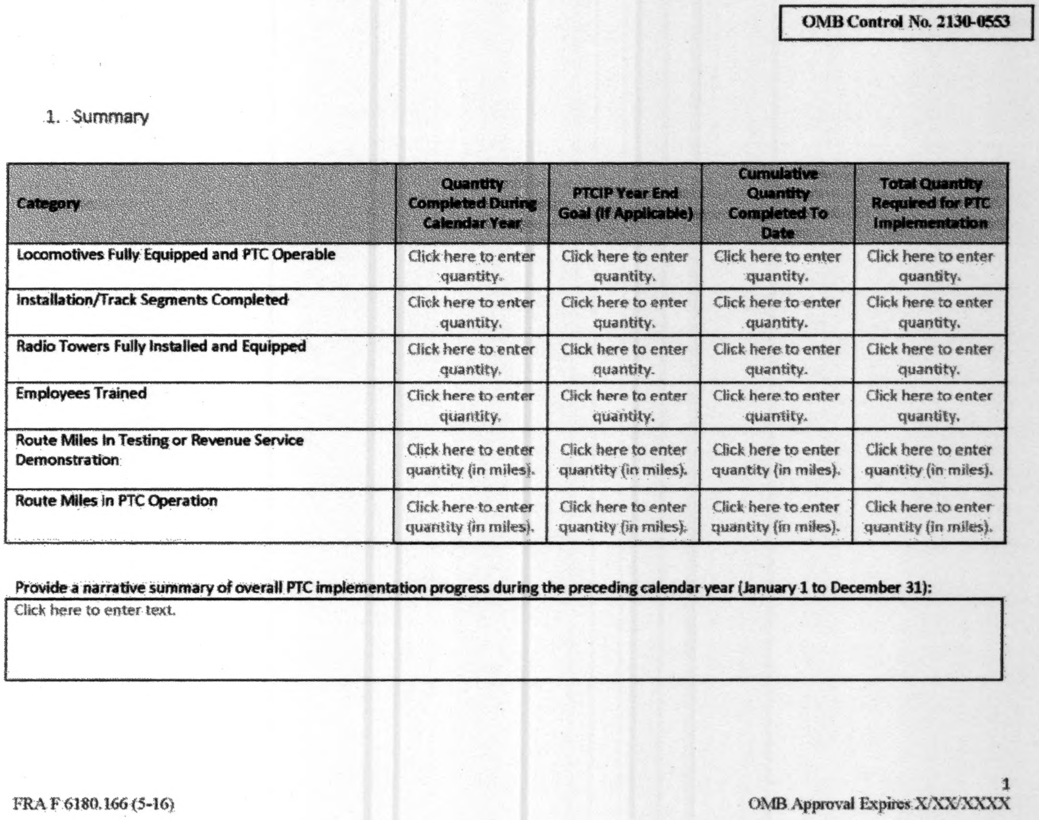
9. **Annual Update for Intercity or Commuter Rail Passenger Transportation (if applicable)** 9

FRA F 6180.166 (5-16) OMB Approval Expires X/XX/XXXX

OMB Control No. 2130-0553

10. Estimated PTC Safety Plan (PTCSP) Submission Date (if not already submitted) 10
11. Testing and Integration Efforts (if applicable, laboratory, integration, and revenue service demonstration) 10
12. Updated Information That FRA Can Use to Maintain Its Geographic Information System (GIS) Database – Only for Track Segments or Route Miles Complete and Operable 10



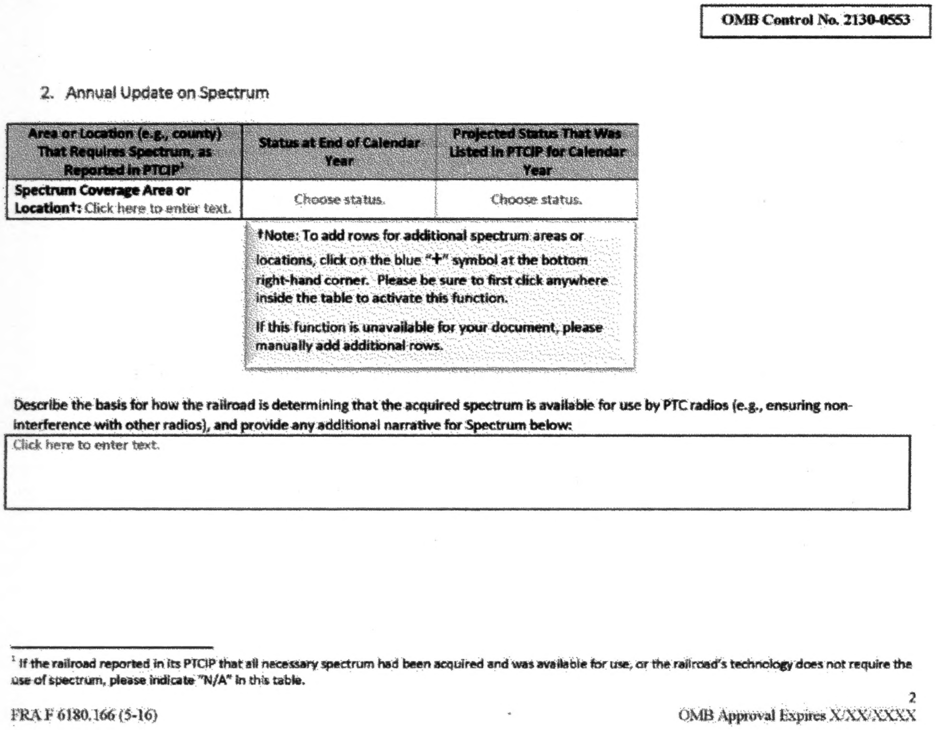
OMB Control No. 2130-0553

1. Summary

Category	Quantity Completed During Calendar Year	PTCIP Year End Goal (If Applicable)	Cumulative Quantity Completed To Date	Total Quantity Required for PTC Implementation
Locomotives Fully Equipped and PTC Operable	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.
Installation/Track Segments Completed	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.
Radio Towers Fully Installed and Equipped	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.
Employees Trained	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.
Route Miles in Testing or Revenue Service Demonstration	Click here to enter quantity (in miles).	Click here to enter quantity (in miles).	Click here to enter quantity (in miles).	Click here to enter quantity (in miles).
Route Miles in PTC Operation	Click here to enter quantity (in miles).	Click here to enter quantity (in miles).	Click here to enter quantity (in miles).	Click here to enter quantity (in miles).

Provide a narrative summary of overall PTC implementation progress during the preceding calendar year (January 1 to December 31):

Click here to enter text.



OMB Control No. 2130-0553

2. Annual Update on Spectrum

Area or Location (e.g., county) That Requires Spectrum, as Reported in PTCIP[1]	Status at End of Calendar Year	Projected Status That Was Listed in PTCIP for Calendar Year
Spectrum Coverage Area or Location†: Click here to enter text.	Choose status.	Choose status.

†Note: To add rows for additional spectrum areas or locations, click on the blue "+" symbol at the bottom right-hand corner. Please be sure to first click anywhere inside the table to activate this function.

If this function is unavailable for your document, please manually add additional rows.

Describe the basis for how the railroad is determining that the acquired spectrum is available for use by PTC radios (e.g., ensuring non-interference with other radios), and provide any additional narrative for Spectrum below:

Click here to enter text.

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[1] If the railroad reported in its PTCIP that all necessary spectrum had been acquired and was available for use, or the railroad's technology does not require the use of spectrum, please indicate "N/A" in this table.

OMB Control No. 2130-0553

3. Annual Update on Major Installations

3.1. Locomotive Status

Category / Installation Feature	Quantity Installed During Calendar Year (Sum of Quarterly Totals)	PTCIP Year End Goal (If Applicable)	Cumulative Quantity Installed	Grand Total Reported in PTCIP (If Applicable)
Locomotive (Apparatus)[2]				
Locomotives with On-board Computers (e.g., Train Management Computer) Installed	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.
Locomotives with PTC Displays Installed	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.
Locomotives with PTC-Capable Event Recorders Installed	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.
Locomotives with Locomotive Radios Installed – Primary Communications (e.g., 220 MHz radios)	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.
Transponder Readers (e.g., for non I-ETMS systems)	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.	Click here to enter quantity.

PTC Software: Describe 1) the railroad's approach to installation of PTC software on its locomotive fleet, and 2) any issues the railroad is experiencing with installed versions of train management software (e.g., reverting back to previous software versions due to errors in the current version):

Click here to enter text.

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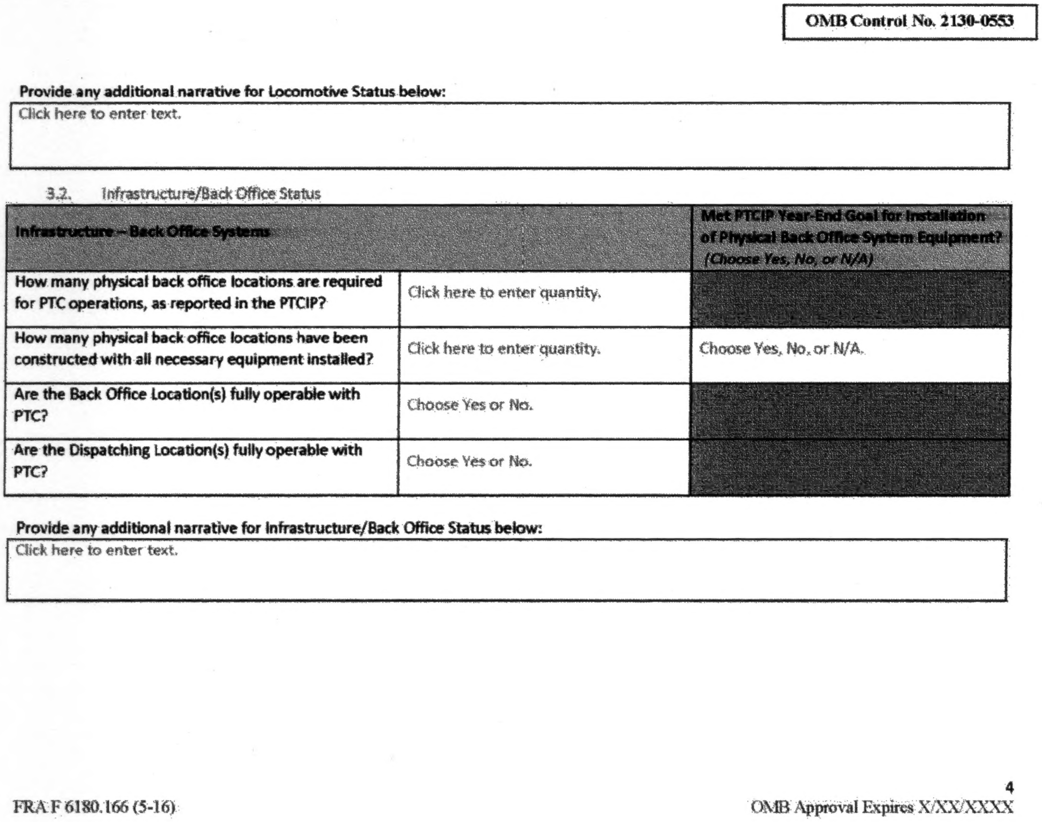
[2] If a particular category listed in this table does not apply to the railroad's technology, please indicate "N/A." A railroad may add categories or subcategories if it wants to provide more detail.



Provide any additional narrative for Locomotive Status below:

Click here to enter text.

3.2. Infrastructure/Back Office Status

Infrastructure – Back Office Systems		**Met PTCIP Year-End Goal for Installation of Physical Back Office System Equipment?** ***(Choose Yes, No, or N/A)***
How many physical back office locations are required for PTC operations, as reported in the PTCIP?	Click here to enter quantity.	
How many physical back office locations have been constructed with all necessary equipment installed?	Click here to enter quantity.	Choose Yes, No, or N/A.
Are the Back Office Location(s) fully operable with PTC?	Choose Yes or No.	
Are the Dispatching Location(s) fully operable with PTC?	Choose Yes or No.	

Provide any additional narrative for Infrastructure/Back Office Status below:

Click here to enter text.

OMB Control No. 2130-0553

3.3. Infrastructure/Wayside Status

Category / Installation Feature	Quantity Installed During Calendar Year (Sum of Quarterly Totals)	PTCIP Year End Goal[3]	Cumulative Quantity Installed	Grand Total Reported in PTCIP
Infrastructure – Wayside Installations (Systemwide)[4]				
Wayside Interface Units	Click here to enter sub quantity.	Click here to enter sub quantity.	Click here to enter sub quantity.	Click here to enter sub quantity.
Communication Towers or Poles	Click here to enter sub quantity.	Click here to enter sub quantity.	Click here to enter sub quantity.	Click here to enter sub quantity.
Switch Position Monitors	Click here to enter sub quantity.	Click here to enter sub quantity.	Click here to enter sub quantity.	Click here to enter sub quantity.
Wayside Radios	Click here to enter sub quantity.	Click here to enter sub quantity.	Click here to enter sub quantity.	Click here to enter sub quantity.
Base Station Radios	Click here to enter sub quantity.	Click here to enter sub quantity.	Click here to enter sub quantity.	Click here to enter sub quantity.
Are all necessary communication backbone utilities (including fiber, copper, ground wiring etc.) installed and ready for operation? Choose Yes or No.				

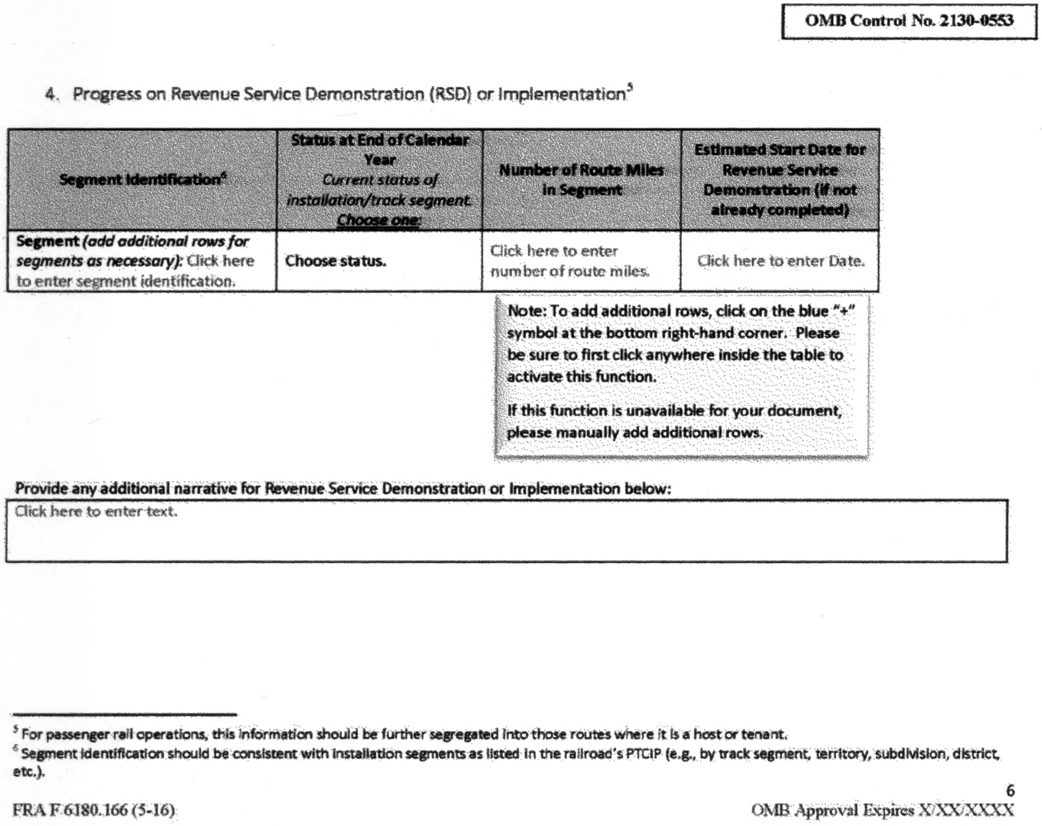
Provide any additional narrative for Installation/Wayside Status below:

Click here to enter text.

---

[3] Unlike the heading in table 3.1, this heading is not qualified with "(If Applicable)" because each railroad was required to provide year-end goals for these particular hardware categories under the PTC Enforcement and Implementation Act of 2015.

[4] If a particular category listed in this table does not apply to the railroad's technology, please indicate "N/A." A railroad may add categories or subcategories if it wants to provide more detail.



OMB Control No. 2130-0553

4. Progress on Revenue Service Demonstration (RSD) or Implementation[5]

Segment Identification[6]	**Status at End of Calendar Year** *Current status of installation/track segment.* ***Choose one:***	**Number of Route Miles in Segment**	**Estimated Start Date for Revenue Service Demonstration (if not already completed)**
Segment ***(add additional rows for segments as necessary):*** Click here to enter segment identification.	**Choose status.**	Click here to enter number of route miles.	Click here to enter Date.

Note: To add additional rows, click on the blue "+" symbol at the bottom right-hand corner. Please be sure to first click anywhere inside the table to activate this function.

If this function is unavailable for your document, please manually add additional rows.

Provide any additional narrative for Revenue Service Demonstration or Implementation below:

Click here to enter text.

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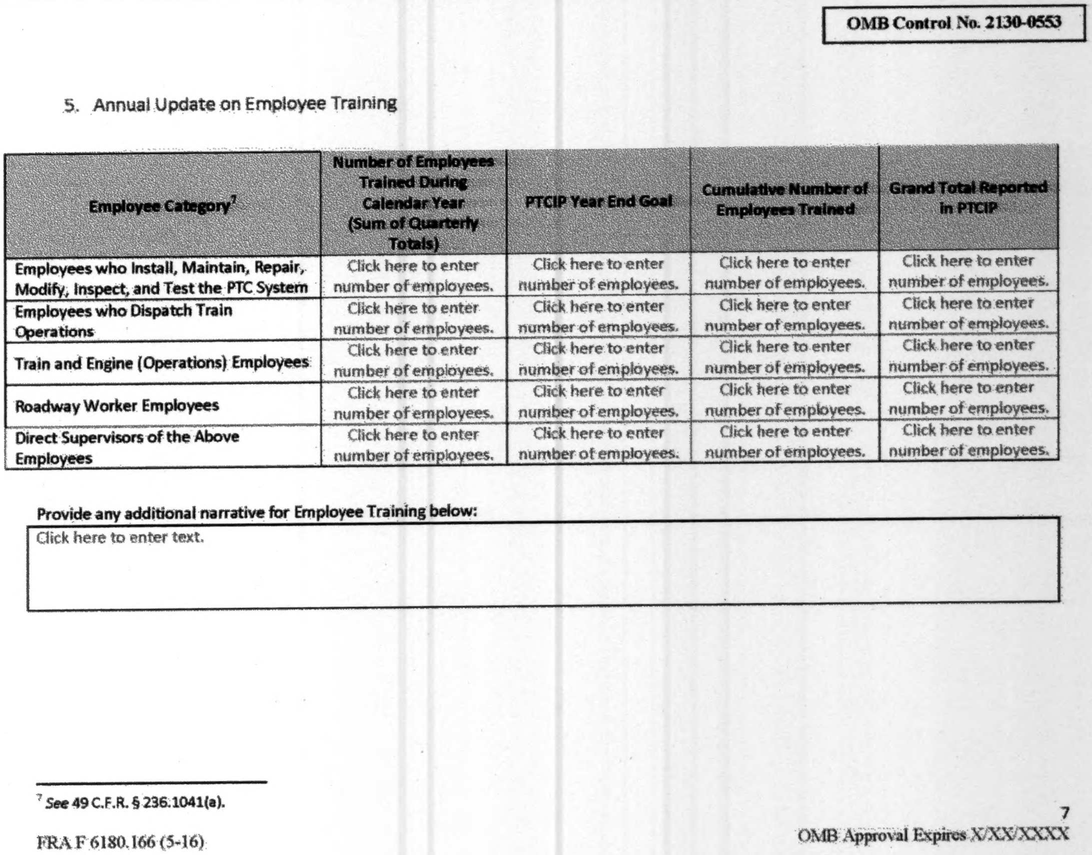
[5] For passenger rail operations, this information should be further segregated into those routes where it is a host or tenant.

[6] Segment identification should be consistent with installation segments as listed in the railroad's PTCIP (e.g., by track segment, territory, subdivision, district, etc.).



OMB Control No. 2130-0553

5. Annual Update on Employee Training

Employee Category[7]	Number of Employees Trained During Calendar Year (Sum of Quarterly Totals)	PTCIP Year End Goal	Cumulative Number of Employees Trained	Grand Total Reported in PTCIP
Employees who Install, Maintain, Repair, Modify, Inspect, and Test the PTC System	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.
Employees who Dispatch Train Operations	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.
Train and Engine (Operations) Employees	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.
Roadway Worker Employees	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.
Direct Supervisors of the Above Employees	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.	Click here to enter number of employees.

Provide any additional narrative for Employee Training below:

Click here to enter text.

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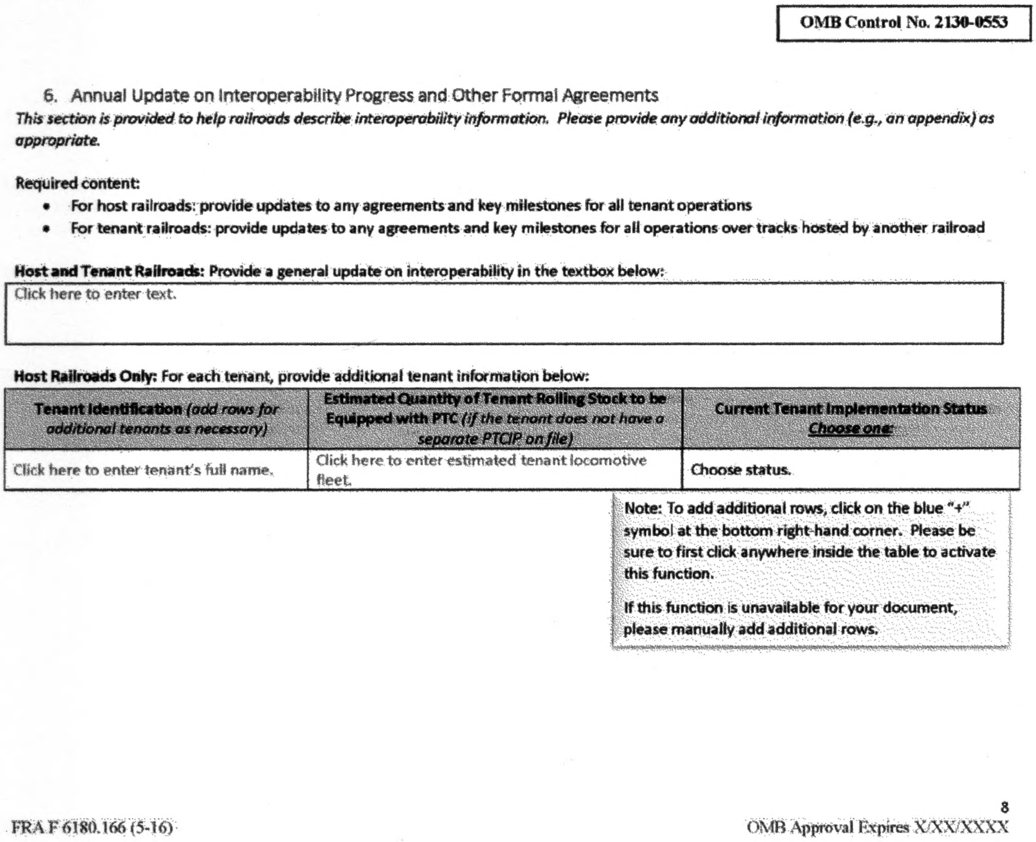
[7] *See* 49 C.F.R. § 236.1041(a).



OMB Control No. 2130-0553

6. Annual Update on Interoperability Progress and Other Formal Agreements

This section is provided to help railroads describe interoperability information. Please provide any additional information (e.g., an appendix) as appropriate.

Required content:

- **For host railroads: provide updates to any agreements and key milestones for all tenant operations**
- **For tenant railroads: provide updates to any agreements and key milestones for all operations over tracks hosted by another railroad**

Host and Tenant Railroads: Provide a general update on interoperability in the textbox below:

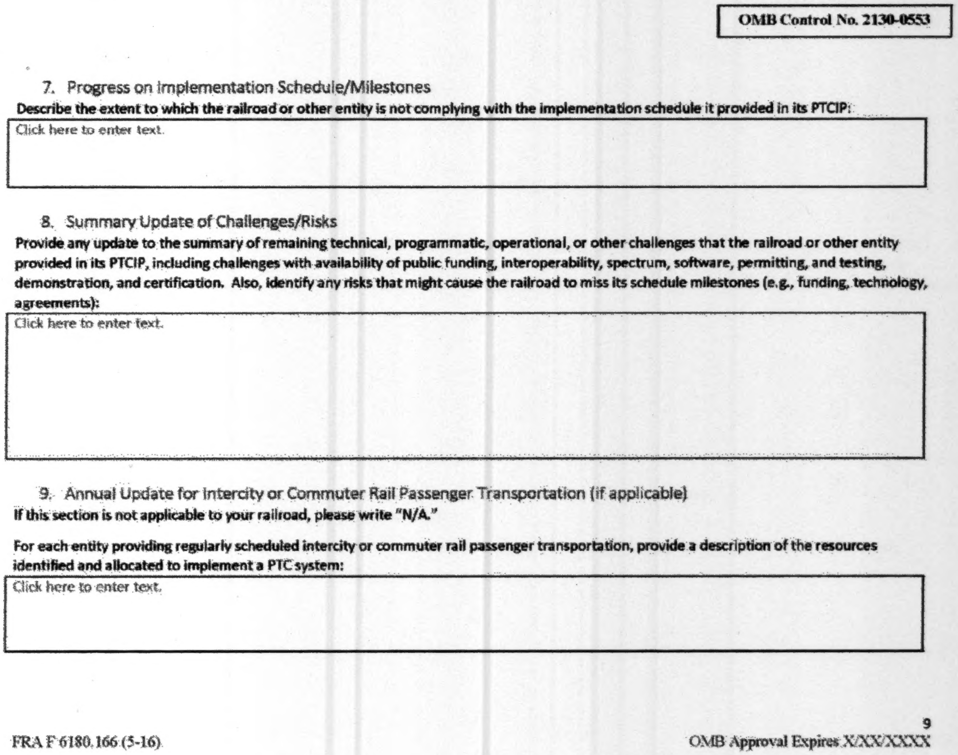
Click here to enter text.

Host Railroads Only: For each tenant, provide additional tenant information below:

Tenant Identification *(add rows for additional tenants as necessary)*	**Estimated Quantity of Tenant Rolling Stock to be Equipped with PTC** *(if the tenant does not have a separate PTCIP on file)*	**Current Tenant Implementation Status** ***Choose one:***
Click here to enter tenant's full name.	Click here to enter estimated tenant locomotive fleet.	Choose status.

Note: To add additional rows, click on the blue "+" symbol at the bottom right-hand corner. Please be sure to first click anywhere inside the table to activate this function.

If this function is unavailable for your document, please manually add additional rows.



OMB Control No. 2130-0553

7. Progress on Implementation Schedule/Milestones

Describe the extent to which the railroad or other entity is not complying with the implementation schedule it provided in its PTCIP:

Click here to enter text.

8. Summary Update of Challenges/Risks

Provide any update to the summary of remaining technical, programmatic, operational, or other challenges that the railroad or other entity provided in its PTCIP, including challenges with availability of public funding, interoperability, spectrum, software, permitting, and testing, demonstration, and certification. Also, identify any risks that might cause the railroad to miss its schedule milestones (e.g., funding, technology, agreements):

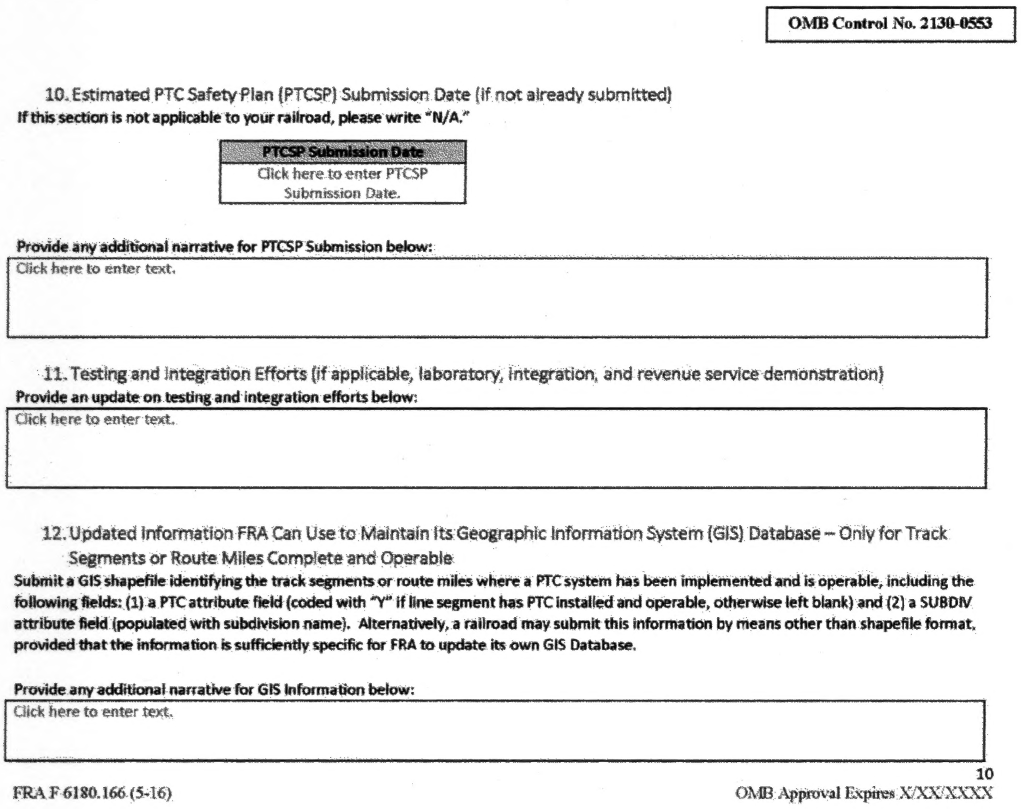
Click here to enter text.

9. Annual Update for Intercity or Commuter Rail Passenger Transportation (if applicable)

If this section is not applicable to your railroad, please write "N/A."

For each entity providing regularly scheduled intercity or commuter rail passenger transportation, provide a description of the resources identified and allocated to implement a PTC system:

Click here to enter text.



10. Estimated PTC Safety Plan (PTCSP) Submission Date (if not already submitted)

If this section is not applicable to your railroad, please write "N/A."

PTCSP Submission Date
Click here to enter PTCSP Submission Date.

Provide any additional narrative for PTCSP Submission below:

Click here to enter text.

11. Testing and Integration Efforts (if applicable, laboratory, integration, and revenue service demonstration)

Provide an update on testing and integration efforts below:

Click here to enter text.

12. Updated Information FRA Can Use to Maintain Its Geographic Information System (GIS) Database – Only for Track Segments or Route Miles Complete and Operable

Submit a GIS shapefile identifying the track segments or route miles where a PTC system has been implemented and is operable, including the following fields: (1) a PTC attribute field (coded with "Y" if line segment has PTC installed and operable, otherwise left blank) and (2) a SUBDIV attribute field (populated with subdivision name). Alternatively, a railroad may submit this information by means other than shapefile format, provided that the information is sufficiently specific for FRA to update its own GIS Database.

Provide any additional narrative for GIS Information below:

Click here to enter text.

OMB Control No. 2130-0553

Public reporting burden for this information collection is estimated to average 38.41 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. According to the Paperwork Reduction Act of 1995, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information unless it displays a currently valid OMB control number. The valid OMB control number for this information collection is **2130-0553**. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection, including suggestions for reducing this burden to: Information Collection Officer, Federal Railroad Administration, 1200 New Jersey Avenue, S.E., Washington D.C. 20590.

[FR Doc. 2016–14890 Filed 6–22–16; 8:45 am]

BILLING CODE 4910–06–C

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. DOT–MARAD–2016–0064]

Request for Comments of a Previously Approved Information Collection

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below is being forwarded to the Office of Management and Budget (OMB) for review and comments. On April 7, 2015, MARAD published an information collection notice with a 60-day comment period (FR 80 18706).

DATES: Comments must be submitted on or before July 25, 2016.

ADDRESSES: Send comments regarding the burden estimate, including suggestions for reducing the burden, to the Office of Management and Budget, Attention: Desk Officer for the Office of the Secretary of Transportation, 725 17th Street NW., Washington, DC 20503. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Lisa Simmons, 202–366–2321, Office of Financial Approvals, Maritime Administration, 1200 New Jersey Avenue SE., Washington, DC 20590. FAX: 202–366–7901 or email: *lisa.simmons@dot.gov.*

SUPPLEMENTARY INFORMATION:

Title: Capital Construction Funds and Exhibits.

OMB Control Number: 2133–0027.

Type of Request: Renewal of a Previously Approved Information Collection.

Abstract: This information collection consists of an application for a Capital Construction Fund (CCF) agreement under 46 U.S.C. Chapter 535 and annual submissions of appropriate schedules and exhibits. The Capital Construction Fund is a tax-deferred ship construction fund that was created to assist owners and operators of U.S.-flag vessels in accumulating the large amount of capital necessary for the modernization and expansion of the U.S. merchant marine. The program encourages construction, reconstruction, or acquisition of vessels through the deferment of Federal income taxes on certain deposits of money or other property placed into a CCF.

Affected Public: United States citizens who own or lease one or more eligible vessels and have a program to provide for the acquisition, construction or reconstruction of a qualified vessel.

Form(s): None.

Estimated Number of Respondents: 143.

Estimated Number of Responses: 143.

Annual Estimated Total Annual Burden Hours: 1790.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.93.

Dated: June 20, 2016.

Gabriel Chavez,

Secretary, Maritime Administration.

[FR Doc. 2016–14906 Filed 6–22–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. DOT–MARAD 2016 0058]

Request for Comments of a Previously Approved Information Collection

AGENCY: Maritime Administration (MARAD), DOT.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below is being forwarded to the Office of Management and Budget (OMB) for review and comments. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on April 7, 2015 (**Federal Register** 18706, Vol. 80, No.66).

DATES: Comments must be submitted on or before July 25, 2016.

FOR FURTHER INFORMATION CONTACT: Dr. David Palmer, (516) 726–5707, U.S. Merchant Marine Academy, Kings Point, NY 11024.

SUPPLEMENTARY INFORMATION:

Title: United States Merchant Marine Academy Alumni Survey.

OMB Control Number: 2133–0542.

Type of Request: Renewal of a Previously Approved Information Collection.

Abstract: 46 U.S.C. 51309 authorizes the Academy to confer academic degrees. To maintain the appropriate academic standards, the program must be accredited by the appropriate accreditation body. The survey is part of USMMA's academic accreditation process.

Affected Public: Graduates of the U.S. Merchant Marine Academy.

Form(s): KP2–66–DK1, KP2–67–DK2, KP2–68–DK3, KP2–69–ENG1, KP2–70–ENG2, KP2–71–ENG3.

Estimated Number of Respondents: 600.

Estimated Number of Responses: 600.

Annual Estimated Total Annual Burden Hours: 150.

ADDRESSES: Send comments regarding the burden estimate, including suggestions for reducing the burden, to the Office of Management and Budget, Attention: Desk Officer for the Office of the Secretary of Transportation, 725 17th Street, NW., Washington, DC 20503. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.93.

By Order of the Maritime Administrator.

Dated: June 16, 2016.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2016–14872 Filed 6–22–16; 8:45 am]

BILLING CODE 4910–81–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
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FEDERAL REGISTER

Vol. 81 Thursday,
No. 121 June 23, 2016

Part II

Environmental Protection Agency

40 CFR Part 60

Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Commercial and Industrial Solid Waste Incineration Units; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[EPA–HQ–OAR–2003–0119; FRL–9945–72–OAR]

RIN 2060–AS11

Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Commercial and Industrial Solid Waste Incineration Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; notice of final action on reconsideration.

SUMMARY: This action sets forth the Environmental Protection Agency's (EPA) final decision on the issues for which it granted reconsideration on January 21, 2015, which pertain to certain aspects of the February 7, 2013, final rule titled "Standards of Performance for New Stationary Sources and Emissions Guidelines for Existing Sources: Commercial and Industrial Solid Waste Incineration Units" (CISWI rule). The EPA is finalizing proposed actions on these four topics: Definition of "continuous emission monitoring system (CEMS) data during startup and shutdown periods;" particulate matter (PM) limit for the waste-burning kiln subcategory; fuel variability factor (FVF) for coal-burning energy recovery units (ERUs); and the definition of "kiln." This action also includes our final decision to deny the requests for reconsideration of all other issues raised in the petitions for reconsideration of the 2013 final commercial and industrial solid waste incineration rule for which we did not grant reconsideration.

DATES: The amendments in this rule to 40 CFR part 60, subpart DDDD, are effective June 23, 2016, and to 40 CFR part 60, subpart CCCC, are effective December 23, 2016. The incorporation by reference of certain publications listed in this rule was approved February 7, 2013.

ADDRESSES: The EPA has established a docket for this action on the commercial and industrial solid waste incineration rule under Docket ID No. EPA–HQ–OAR–2003–0119. All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the EPA Docket Center, EPA West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744 and the telephone number for the Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For further information, contact Dr. Nabanita Modak Fischer, Fuels and Incineration Group, Sector Policies and Programs Division (E143–05), Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5572; fax number: (919) 541–3470; email address: *modak.nabanita@epa.gov.*

SUPPLEMENTARY INFORMATION:

Organization of This Document. The following outline is provided to aid in locating information in this preamble.

I. General Information
  A. Does this reconsideration action apply to me?
  B. How do I obtain a copy of this document and other related information?
  C. Judicial Review
II. Summary of Final Amendments
  A. Background Information
  B. Actions We Are Taking
  C. Other Actions We Are Taking
III. Summary of Significant Changes Since Proposal
IV. Summary of Significant Comments and Responses
  A. Definition of "CEMS Data During Startup and Shutdown Periods"
  B. PM Limit for the Waste-Burning Kiln Subcategory
  C. FVF for Coal-Burning Energy Recovery Units
  D. Definition of "Kiln"
V. Technical Corrections and Clarifications
  A. 2000 CISWI New Source Applicability Clarification for Incinerators and Air Curtain Incinerators
  B. Typographical Errors and Corrections
  C. Clarifications
VI. Environmental, Energy and Economic Impacts
VII. Statutory and Executive Order Reviews
  A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
  B. Paperwork Reduction Act (PRA)
  C. Regulatory Flexibility Act (RFA)
  D. Unfunded Mandates Reform Act (UMRA)
  E. Executive Order 13132: Federalism
  F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
  G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
  H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
  I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR part 51
  J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
  K. Congressional Review Act (CRA)

Preamble Acronyms and Abbreviations. The following acronyms and abbreviations are used in this document.

Btu	British thermal unit
CAA	Clean Air Act
CBI	Confidential business information
Cd	Cadmium
CEMS	Continuous emissions monitoring systems
CFR	Code of Federal Regulations
CISWI	Commercial and Industrial Solid Waste Incineration
CO	Carbon monoxide
CO_2	Carbon dioxide
CPMS	Continuous Parameter Monitoring System
dscm	Dry standard cubic meter
EG	Emission Guidelines
EJ	Environmental Justice
EPA	U.S. Environmental Protection Agency
ERU	Energy recovery unit
ESP	Electrostatic precipitator
FVF	Fuel variability factor
HCl	Hydrogen chloride
Hg	Mercury
ICR	Information collection request
MACT	Maximum achievable control technology
mg/dscm	Milligrams per dry standard cubic meter
mmBtu/hr	Million British thermal units per hour
NAICS	North American Industrial Classification System
NESHAP	National emission standards for hazardous air pollutants
ng/dscm	Nanograms per dry standard cubic meter
NHSM	Non-hazardous secondary material(s)
NO_X	Nitrogen oxides
NSPS	New source performance standards
NTTAA	National Technology Transfer and Advancement Act
OAQPS	Office of Air Quality Planning and Standards
OMB	Office of Management and Budget
Pb	Lead
PM	Particulate matter (filterable, unless otherwise specified)
ppm	Parts per million
ppmv	Parts per million by volume
ppmvd	Parts per million by dry volume
PS	Performance Specification
RCRA	Resource Conservation and Recovery Act
RIN	Regulatory Information Number
SBA	Small Business Administration
SO_2	Sulfur dioxide

SSM Startup, shutdown, and malfunction
The Court United States Court of Appeals for the District of Columbia Circuit
TTN Technology Transfer Network
ug/dscm Micrograms per dry standard cubic meter
UMRA Unfunded Mandates Reform Act
U.S.C. United States Code
VCS Voluntary consensus standards
WWW World Wide Web

I. General Information

A. Does this reconsideration action apply to me?

Categories and entities potentially affected by the proposed action are those that operate Commercial and Industrial Solid Waste Incineration (CISWI) units. The New Source Performance Standards (NSPS) and Emission Guidelines (EG), hereinafter referred to as "standards," for CISWI affect the following categories of sources:

Category	NAICS[1] code	Examples of potentially regulated entities
Any industrial or commercial facility using a solid waste incinerator.	211, 212, 486	Mining; oil and gas exploration operations; pipeline operators.
	221	Utility providers.
	321, 322, 337	Manufacturers of wood products; manufacturers of pulp, paper and paperboard; manufacturers of furniture and related products.
	325, 326	Manufacturers of chemicals and allied products; manufacturers of plastics and rubber products.
	327	Manufacturers of cement; nonmetallic mineral product manufacturing.
	333, 336	Manufacturers of machinery; manufacturers of transportation equipment.
	423, 44	Merchant wholesalers, durable goods; retail trade.

[1] North American Industrial Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this final action. To determine whether your facility would be affected by this final action, you should examine the applicability criteria in 40 CFR 60.2010 of subpart CCCC, 40 CFR 60.2505 of subpart DDDD and 40 CFR part 241. If you have any questions regarding the applicability of this final action to a particular entity, contact the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. How do I obtain a copy of this document and other related information?

The docket number for this final action regarding the CISWI NSPS (40 CFR part 60, subpart CCCC) and EG (40 CFR part 60, subpart DDDD) is Docket ID No. EPA–HQ–OAR–2003–0119. In addition to being available in the docket, an electronic copy of this final action is available on the World Wide Web (WWW) through the Technology Transfer Network (TTN) Web. Following signature, the EPA posted a copy of the proposed action at *http://www.epa.gov/ttn/atw/129/ciwi/ciwipg.html.* The TTN provides information and technology exchange in various areas of air pollution control.

C. Judicial Review

Under the CAA section 307(b)(1), judicial review of this final rule is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) by August 22, 2016. Under CAA section 307(d)(7)(B), only an objection to this final rule that was raised with reasonable specificity during the period for public comment can be raised during judicial review. Any person seeking to make such a demonstration to us should submit a Petition for Reconsideration to the Office of the Administrator, Environmental Protection Agency, Room 3000, Ariel Rios Building, 1200 Pennsylvania Ave. NW., Washington, DC 20004, with a copy to the persons listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20004. Note, under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce these requirements.

II. Summary of Final Amendments

A. Background Information

On March 21, 2011, the EPA promulgated revised NSPS and EG for CISWI units. Following that action, the Administrator received petitions for reconsideration that identified certain issues that warranted further opportunity for public comment. In response to the petitions, the EPA reconsidered and requested comment on several provisions of the February 2011 final NSPS and EG for commercial and industrial solid waste incineration units. The EPA published the proposed revisions to the NSPS and EG for commercial and industrial solid waste units on December 23, 2011 (76 FR 80452).

On February 7, 2013, the EPA promulgated the final reconsidered NSPS and EG for CISWI units (78 FR 9112). The final rule made some revisions to the December 2011 proposed reconsideration rule in response to comments and additional information received. Following that action, the EPA again received petitions for reconsideration. These petitions stated certain provisions should be reconsidered and that the public lacked sufficient opportunity to comment on some of the provisions contained in the final 2013 CISWI rule. On January 21, 2015, the EPA reconsidered and requested comment on four provisions of the 2013 final NSPS and EG for CISWI units. Additionally, the EPA proposed clarifying changes and corrections to the final rule, some of which were raised in petitions for reconsideration of the 2013 CISWI rule. The EPA also proposed to amend the final rule by removing the affirmative defense provision. The EPA continued to evaluate the remaining issues raised in the petitions for reconsideration of the February 7, 2013 final CISWI reconsideration based on public comments received on the January 21, 2015, proposed reconsideration. For a more detailed background and additional information on how this rule is related to other CAA combustion rules issued under CAA section 112 and the Resource Conservation and Recovery Act (RCRA) definition of solid waste, refer to prior notices (76 FR 15704, 78 FR 9112).

B. Actions We Are Taking

In this document, we are finalizing amendments associated with certain issues raised by Petitioners in their petitions for reconsideration on the 2013 CISWI rule. These provisions are: (1) Definition of "CEMS data during startup and shutdown periods;" (2) particulate matter (PM) limit for the waste-burning kiln subcategory; (3) fuel variability factor (FVF) for coal-burning energy recovery units (ERUs); and (4) the definition of "kiln." The final amendments are summarized as follows:

1. Definition of "CEMS data during startup and shutdown periods": The EPA is revising the "CEMS data during startup and shutdown" definition to be subcategory-specific. For ERUs and waste-burning kilns, the definitions reflect provisions similar to those of the non-waste counterpart National Emission Standards for Hazardous Air Pollutants (NESHAP) to CISWI for the type of source (*i.e.,* boilers and cement kilns). Therefore, ERUs will comply with provisions similar to those in the major source Boiler NESHAP, and waste-burning kilns will comply with provisions similar to those in the Portland Cement NESHAP. For incinerators and small remote incinerators, the proposed definition (*i.e.,* from a cold start and up to 48 hours for startup and 24 hours or less for shutdown) will apply.

2. Particulate matter limit for the waste-burning kiln subcategory: The EPA has determined that the test averages, instead of the individual test runs, should be used to establish the standards for new and existing waste-burning kilns. Based on that approach, the final PM emission limits for existing kilns is 13.5 mg/dscm and the final PM emission limit for new kilns is 4.9 mg/dscm.

3. Fuel variability factor (FVF) for coal-burning energy recovery units: The EPA is incorporating a fuel variability factor and adopting as final the emission limits discussed in the proposed rule for cadmium (Cd), hydrogen chloride (HCl), mercury (Hg), lead (Pb), filterable particulate matter (PM), and nitrogen oxides (NO_X). Additionally, the EPA has re-evaluated the fuel sulfur data with paired sulfur dioxide (SO_2) data and is incorporating a FVF into the floor calculations for SO_2. The final SO_2 limit for existing and new coal ERUs is 850 parts per million by dry volume (ppmvd).

4. Definition of "kiln": The EPA is finalizing a definition of "kiln" that is consistent with that of the Portland Cement NESHAP. The terms "in-line raw mill" and "in-line coal mill" are included in the definition, and, therefore, have been added to the definitions within the CISWI rule. Furthermore, the EPA is finalizing the proposed compliance demonstration and ongoing monitoring method for waste-burning kilns that combine emission streams from the in-line raw mill and/or the in-line coal mill and exhaust through multiple stacks. The EPA is also finalizing clarifying language that makes the monitoring requirements for waste-burning kilns consistent with those in the Portland Cement NESHAP. Specifically, we are not requiring that CEMS or PM continuous parameter monitoring systems (CPMS) be installed on separate alkali bypass or in-line coal mill stacks. Instead, as is the case with the Portland Cement NESHAP, the results of the initial and subsequent performance tests for the alkali bypass and in-line coal mill stacks can be used to determine the combined emissions to demonstrate compliance with the relevant emissions limit. However, unlike the Portland Cement NESHAP, the performance test must be conducted on an annual basis (between 11 and 13 calendar months following the previous performance test) to keep the testing schedule for these stacks consistent with the CISWI rule's annual performance testing requirements.

Section IV of this preamble discusses these issues in further detail and presents the revisions necessary to address each issue.

Additionally, the EPA is clarifying certain applicability provisions relating to incinerator units and air curtain incinerator units subject to the 2000 CISWI NSPS and is correcting various typographical errors identified in the rule as published in the CFR. Section V of this preamble discusses these issues in further detail.

The EPA is also finalizing the proposed amendments to the final rule by removing the affirmative defense provision for the reasons set forth in the proposed rule. *See* 80 FR 3018, 3025 (January 21, 2015).

C. Other Actions We Are Taking

Section 307(d)(7)(B) of the CAA states that "[o]nly an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. If the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within such time or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule, the Administrator shall convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed. If the Administrator refuses to convene such a proceeding, such person may seek review of such refusal in the United States court of appeals for the appropriate circuit (as provided in subsection (b))."

As to the first procedural criterion for reconsideration, a petitioner must show why the issue could not have been presented during the comment period, either because it was impracticable to raise the issue during that time or because the grounds for the issue arose after the period for public comment (but within 60 days of publication of the final action). The EPA is denying the petitions for reconsideration on a number of issues because this criterion has not been met. In many cases, the petitions reiterate comments made on the proposed December 2011 rule during the public comment period for that rule. On those issues, the EPA responded to those comments in the final rule and made appropriate revisions to the proposed rule after consideration of public comments received. It is well established that an agency may refine its proposed approach without providing an additional opportunity for public comment. *See Community Nutrition Institute* v. *Block,* 749 F.2d at 58 and *International Fabricare Institute* v. *EPA,* 972 F.2d 384, 399 (D.C. Cir. 1992) (notice and comment is not intended to result in "interminable back-and-forth[,]" nor is an agency required to provide additional opportunity to comment on its response to comments) and *Small Refiner Lead Phase-Down Task Force* v. *EPA,* 705 F.2d 506, 547 (D.C. Cir. 1983) ("notice requirement should not force an agency endlessly to repropose a rule because of minor changes").

In the EPA's view, an objection is of central relevance to the outcome of the rule only if it provides substantial support for the argument that the promulgated regulation should be revised. *See Union Oil* v. *EPA,* 821 F.2d 768, 683 (D.C. Cir. 1987) (court declined to remand rule because petitioners failed to show substantial likelihood that final rule would have been changed based on information in petition). *See* also the EPA's Denial of the Petitions to Reconsider the Endangerment and Cause or Contribute Findings for Greenhouse Gases under Section 202 of the Clean Air Act, 75 FR at 49556, 49561 (August 13, 2010). *See* also 75 FR at 49556, 49560–49563 (August 13, 2010) and 76 FR at 4780, 4786–4788 (January 26, 2011) for additional discussion of the standard for reconsideration under CAA section 307(d)(7)(B).

This action includes our final decision to deny the requests for reconsideration with respect to all issues raised in the petitions for reconsideration of the final 2013 CISWI rule for which we did not grant reconsideration. These denied requests for reconsideration are discussed in detail in the "Reconsideration issues on the 2013 final rule" memorandum found in the docket to this rulemaking.

III. Summary of Significant Changes Since Proposal

The EPA did not propose revisions to the definition of "CEMS data during startup and shutdown," but requested comment and suggestions for provisions in this definition that would address the transitional operation period at startup. Based on our review of comments received and suggestions on provisions, we are finalizing revised subcategory-specific definitions for "CEMS data during startup and shutdown" that are operationally representative for the subcategory of unit, and more closely resemble the non-waste burning regulatory definitions of these periods of operation. This issue, and the rationale for doing so, are discussed in greater detail in section IV.A. of this preamble.

Similarly, the EPA did not propose PM emission limits for waste-burning kilns based on test average data instead of test run data, but requested comment on the appropriateness of such an approach for this set of data. Upon consideration of comments, the EPA has determined to adopt the emission limits based on test average data for PM for the waste-burning kiln subcategory, and we have discussed our rationale for this in section IV.B. of this preamble.

The EPA did not propose but requested comment and additional data concerning the need for a FVF for coal-fired ERUs. Potential emission limits based on periods of non-waste combustion and, if applicable, a FVF for coal ERUs were discussed in the proposal for coal-burning ERUs for Cd, HCl, Hg, Pb, PM, and NO_X. Based on comments and additional analysis, the EPA is adopting these emission limits and also incorporating a FVF into the floor calculations for the SO_2 emission limit. The EPA did not discuss a FVF for SO_2 at proposal because the sulfur data the EPA had intended to use to develop the FVF appeared to have only one data point that could be paired with SO_2 emissions test data. It was brought to the EPA's attention during the comment period, however, that there were in fact two data points in the sulfur data set that could be paired with emissions test data. It was not initially clear that the coal samples dated 4–9 days prior to the emissions test were paired samples. However, during the comment period, a commenter informed the EPA these data were paired and the different dates were due to the lag time between sampling and actual combustion. This clarification enabled the EPA to determine that sufficient paired data exist for the calculation of a FVF for SO_2, which resulted in a revised SO_2 emission limit of 850 ppmvd for new and existing coal ERUs. Consistent with the January 21, 2015 proposal, the EPA is adopting this revised emission limit to account for the fuel variability for this subcategory of CISWI units. Section IV.C of this preamble discusses this issue in further detail and responds to comments on the issue.

Additionally, the HCl CEMS requirements for waste-burning kilns not equipped with acid gas wet or dry scrubbers have been revised in response to comments and to be more consistent with more recently promulgated monitoring provisions included in the Portland Cement NESHAP rule. These revised provisions allow sources to use CEMS installed and operated according to either Performance Specification 15 or Performance Specification 18 to continuously monitor HCl emissions. The revised provisions also provide additional clarification and detail to sources on the procedures to use for calibrating and verifying the performance of the HCl CEMS.

IV. Summary of Significant Comments and Responses

This section of the preamble summarizes the major comments received regarding the reconsidered issues and the EPA's responses in support of this final rule. For other comments not discussed here, refer to the "Summary of Public Comments and Responses for Commercial and Industrial Solid Waste Incineration Units: 2015 Reconsideration and Final Amendments" in the docket.

A. Definition of "CEMS Data During Startup and Shutdown Periods"

Background: In the January 21, 2015, proposal, the EPA requested comments on the definition of "CEMS data during startup and shutdown" that was in the February 2013 final rule. As background, the 2011 CISWI final rule contained CEMS monitoring requirements for carbon monoxide (CO) from new sources, including a provision that mandated a 7 percent oxygen correction. After the 2011 CISWI final rule was published, petitioners indicated that correcting CO concentration measurements to 7 percent oxygen is problematic during startup and shutdown periods when the flue gas oxygen content approaches the oxygen content of ambient air, especially with regard to the ERU subcategory. Oxygen contents are often maintained relatively close to ambient air during combustion unit startup and shutdown in order to safely operate the unit, but, as a result, the corrected CO values during these periods are artificially inflated due to the oxygen correction calculation. Petitioners presented data that demonstrated how these inflated data points drive the 30-day rolling average values beyond the emission limit.

To resolve this issue, the EPA determined that the 7 percent oxygen correction would not be required for CEMS data collected during periods of startup and shutdown, referred to and defined as "CEMS data during startup and shutdown."

Based on data submitted for coal-burning ERUs, a new definition of "CEMS data during startup and shutdown" was proposed in the December 2011 reconsideration proposal that referred to the data collected during the first 4 hours of operation of an energy recovery unit starting up from a cold start and the hour of operation following the cessation of waste material being fed to the unit during shutdown.

The EPA received comments on the proposed definition expressing concern that the time limits included in the definition may not accurately represent all CISWI unit types. Further, commenters argued that the same logic should apply for all CEMS-measured emission limits, not just CO. They explained that, even though CEMS is a compliance alternative rather than a requirement for most CISWI standards, other air regulations and permit requirements may require the units to continue to monitor emissions using CEMS data. Therefore, in the February 2013 CISWI final rule, the definition was revised to include all pollutants measured with a CEMS, expanded to include a separate definition for waste-burning kilns, and revised to remove the 4-hour and 1-hour time limits in the definition. Within that definition, the EPA defined the end of the startup period and the beginning of the shutdown period as the introduction and cessation of waste fed to the unit, respectively. Information available for the best performing units described their typical operation and supported defining the startup and shutdown periods based on the introduction and cessation of waste being fed to the units. Furthermore, for the incinerator, small remote incinerator, and the ERU subcategories, the February 2013 action specified an upper limit of 48 hours for startup periods and 24 hours for shutdown periods of CEMS data, consistent with information provided by commenters.

After the February 2013 CISWI final rule was promulgated, the EPA received petitions stating that stakeholders did not have the opportunity to comment on the final definition, especially the clause that defines the beginning and ending of these periods as the introduction and cessation, respectively, of waste material being fed to the combustor. Petitioners argued that, with the inclusion of the provision ending startup when waste is added to the unit, the end of startup will occur too early because units that combust waste often introduce waste before steady state operations to transition from startup fuel to waste and other primary fuel combustion. For this reason, the petitioners argued that the EPA should extend the startup period duration to include the period of time when sources are transitioning to waste combustion from the startup fuel.

On January 21, 2015, the EPA requested comment on whether the definition should be revised to extend the startup period to include this transitional period of combustor operation. In addition, the EPA requested that commenters suggest provisions that would ensure adequate application of the CEMS data during startup and shutdown definition, such as maximum allowable time limits after introduction of waste, if the agency were to allow solid waste combustion during startup.

Comment: Several commenters supported, to a degree, the EPA's change in the 2013 final rule from the proposed 4-hour and 1-hour time limits on the definitions of CEMS data during startup and shutdown to the more subcategory-specific definitions found in the 2013 final rule, but suggested additional revisions to make the definition more accurately reflect these periods for certain types of units. Commenters noted technical reasons during startup that cause corrected emissions concentrations to possibly show emissions in excess of those occurring during normal, steady-state operation due to the 7 percent oxygen correction. These reasons included: (1) Stack oxygen levels approach ambient levels, inflating oxygen correction factors even though mass emission rates are low; (2) the combustor has not attained optimal temperature, turbulence, and residence time conditions, which are key factors for control of combustion-related emissions; and (3) air pollution control equipment has not achieved necessary minimum temperature and/or other operating conditions necessary for effective steady-state performance on which the standards are based. The commenters also asserted that, while elevated emissions do occur during startups, the magnitude and period of elevated emissions will be actively minimized as required by the "general duty" provisions to minimize emissions at all times including startups and shutdowns. Additionally, the commenters argued that, for ERUs, at least, unit operators are economically motivated to minimize the duration of any startups, because the shorter the startup, the quicker a unit can be brought online to sell steam and/or connect to the grid and sell power. Also with respect to ERUs, commenters stated that units firing solid material on grates or in fluidized beds require more time for the material to fully ignite and achieve the optimal combustion conditions than gaseous or liquid-fired units do. The commenters stated that elevated corrected emission concentrations following initial solid material firing is an inherent characteristic of ERU subcategories such as stoker and fluidized bed biomass ERUs. In conclusion, the commenters recommended that, given the virtually identical technologies used for both boilers and CISWI ERUs, the EPA should incorporate language in the CEMS data definition similar to that which it proposed in the major source and area source Boiler NESHAP rules. One commenter provided mark-up language reflecting major source boiler language in the "CEMS data for startup and shutdown" definition that would apply specifically to CISWI ERUs, and a separate definition that could apply to incinerators and small remote incinerators. For ERUs, the commenter suggested the following definition, which eliminates the "cold start" and "until waste is fed to the unit" language, and adds the concept of tying the CEMS data during startup period to the time that useful thermal energy is generated.

The commenter suggested that CEMS data during startup and shutdown should be defined as follows:

For energy recovery units: CEMS data collected during the first hours of operation of a CISWI unit startup including the hours of operation firing non-waste fuel and the hours following introduction of waste to the unit until 4 hours after when the ERU makes useful thermal energy (such as steam or heat) for heating, cooling, and process purposes, or generates electricity, whichever is earlier, and the hours of operation following the cessation of waste material being fed to the CISWI unit during a unit shutdown. For each startup event, the length of time that CEMS data may be claimed as being CEMS data during startup must be 48 operating hours or less. For each shutdown event, the length of time that CEMS data may be claimed as being CEMS data during shutdown must be 24 operating hours or less.

As an alternative to the above definition, the commenter suggested the definition could include the period of time up to 6 hours following introduction of waste to the unit instead of tying the definition to "useful thermal energy." The commenter noted that this might allow the definition to be applicable to incinerators and small remote incinerators.

Another commenter suggested that the first 48 hours of startup and the last 24 hours of shutdown for incinerators, small remote incinerators, and energy recovery units is adequate in most cases. This commenter stated that any time the feed to a combustion chamber is modified (*e.g.*, new material added, same material with higher or lower feed rates), the combustion process is disturbed. The commenter further stated that the length of time it takes for the combustion process to re-stabilize depends upon a number of factors (size of the combustion unit, amount of waste introduced, the Btu content of the waste introduced, the combustibility of that waste, the operating conditions, etc.). Therefore, the commenter recommended that the CEMS data during startup and shutdown are best decided on a site-specific basis and urged the EPA to allow this as an option.

With respect to waste-burning kilns, one commenter argued that it is highly beneficial to have the definitions of startup and shutdown for kilns in the CISWI rule match the definitions in the Portland Cement NESHAP. Therefore, the commenter supported having a separate definition of CEMS data during startup and shutdown that applied to waste-burning kilns, and that this definition should also reflect provisions found in the Portland Cement NESHAP. The commenter provided the following language as a suggestion on what would be appropriate, and also suggested a corresponding footnote to clarify that the 7 percent oxygen adjustment need not be applied during periods of startup and shutdown:

"*CEMS data during startup and shutdown* means the following: (2) For waste-burning kilns: CEMS data collected during the periods of kiln operation that do not include normal operations. Startup means the time from when a shutdown kiln first begins firing fuel until it begins producing clinker. Startup begins when a shutdown kiln turns on the induced draft fan and begins firing fuel in the main burner. Startup ends when feed is being continuously introduced into the kiln for at least 120 minutes or when the feed rate exceeds 60 percent of the kiln design limitation rate, whichever occurs first. Shutdown means the cessation of kiln operation. Shutdown begins when feed to the kiln is halted and ends when continuous kiln rotation ceases."

Response: Based on these comments and the EPA's goal to provide, where appropriate, consistent regulatory provisions, the EPA has determined to revise the definition of "CEMS data during startup and shutdown" to be subcategory-specific. For ERUs and waste-burning kilns, for example, the definition will reflect definitions similar to those of the non-waste counterpart NESHAP to CISWI for the type of source. Therefore, the final definition for ERUs will reflect provisions found in the major source Boiler NESHAP, and the final definition for waste-burning kilns will reflect provisions similar to those in the Portland Cement NESHAP. For incinerators and small remote incinerators, the proposed definition (*i.e.,* from a cold start and up to 48 hours for startup and 24 hours or less for shutdown) will still apply. These subcategory-specific definitions provide a consistent basis for ERUs and kilns that may change applicability periodically so that owners and operators will have a consistent requirement for demonstrating compliance regardless of the mode (waste or non-waste) the unit is being operated in. Furthermore, for incinerators and small remote incinerators, industry commenters are confident that the full range of these sources will be able to maintain compliance with these time allowances that were proposed.

We note that certain commenters indicate that reasons for changing the definitions include that the units may have greater emissions during startup and shutdown and also that pollution control equipment may not be fully operational during startup. The EPA is not revising the definitions to allow sources to violate the standard; instead the change is designed to better reflect the actual operating conditions during startup and shutdown. The oxygen correction is thus designed to allow sources to use actual stack oxygen levels during these periods instead of numbers corrected to 7 percent oxygen.[1] If sources believe that, even with the stack oxygen correction, emissions will exceed the levels of the standard because of incomplete combustion or because air pollution controls are not fully operational, they must take steps (*e.g.,* burn clean startup fuel for longer periods) to ensure compliance.

Finally, the subcategory-specific definitions of "CEMS data during startup and shutdown" in this final rule more clearly specify the beginning and end of startup and shutdown periods for each subcategory of CISWI unit. However, we realize in doing so that the previous, separate definitions of "startup period" and "shutdown" that have been held over from the 2000 CISWI rule may now cause confusion for waste-burning kilns and ERUs especially. Because the 2000 CISWI rule applied to incinerator units (and not ERUs and waste-burning kilns), we recognize the need to clarify that the "startup period" and "shutdown" definitions apply only to incinerators and small, remote incinerators. For this reason, the EPA is revising the definitions of "startup period" and "shutdown" to clarify that they are intended to apply only to incinerators and small, remote incinerators.

Comment: One commenter argued that allowing sources to comply with emissions standards based on uncorrected emissions measurements would be unlawful and arbitrary. The commenter explained that the EPA does not claim that all units will have oxygen levels close to the ambient air, that any units' oxygen levels will actually be at the level of the ambient air during these periods, or that any units' oxygen levels will be at that high level consistently. The commenter suggested that the EPA should instead consider several other approaches. First, the commenter suggested that the EPA could require sources to show compliance during these periods using another method, such as stack tests. The commenter stated that the EPA recognized that CEMS are a compliance alternative rather than a requirement for most CISWI standards. The commenter also argued that the EPA stated it is maintaining CEMS as a compliance alternative during these periods because "other air regulations and permit requirements may require" CEMS data. However, the commenter argued that the EPA did not state what these other requirements are, or why the same CEMS problems it has identified here do not apply to them. The commenter further argued that even if other regulatory requirements do require sources to maintain CEMS data, that does not compel the EPA to accept their data as demonstrative of compliance with the requirements of the performance standards and emissions guidelines for air pollution from CISWI. The commenter also suggested that, if the CEMS compliance alternative were retained, the EPA could require sources to correct their measurements to the level of oxygen actually present, as measured by an oxygen analyzer or another method. Finally, the commenter offered as an alternative that the EPA could develop mass-based limits instead of concentration-based limits, which do not require oxygen correction. The commenter concluded that, because the EPA has not even considered these alternatives, the proposal to allow sources to show compliance based on measurements it does not dispute will be inaccurate is arbitrary as well as unlawful.

Response: As we noted in the proposed rule, the rules generally require stack emissions testing. These tests can span several hours. The CISWI rule emission limits were based on data obtained during normal operations, which is also what the rule requires for conducting performance testing (*see* 40 CFR 60.2125(a) and 40 CFR 60.2690(a)). As has been noted in other comments and in the costing analyses presented in support of the CISWI rulemaking, the emission testing program is not trivial in cost and effort. Therefore, adding a requirement for additional stack testing during startup and shutdown periods, which seems to be what this commenter suggests, would further add to the compliance cost of the rule for obtaining data for a small portion of the source's operations. The EPA does not believe this additional monitoring is required to assure compliance with the standards.

As noted before and by some commenters, monitoring by CEMS is an alternative, and may be useful for sources that are required by permit or for Acid Rain program requirements (40

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[1] Stack oxygen data must still be measured during these periods, but since a correction to stack oxygen essentially means multiplying the measured concentration by 1, the concentration value measured at stack oxygen is used to calculate average concentrations.

CFR part 75) to continually monitor emissions of certain pollutants, primarily NO_X and SO_2. The EPA realized that the interaction of newly applicable CISWI standards to ERUs and waste-burning kilns may differ from existing requirements for these sources developed under the Acid Rain program, permit requirements enacted for state or local conditions, or even under various consent decrees. The EPA also recognizes that different programs measure and evaluate emissions for various purposes and in differing formats (*e.g.,* lb/MMBtu), and therefore disagrees with the commenter's assertions that if these other programs do not need these provisions, then neither should CISWI. In fact, the EPA maintains that the reasons other programs may not require separate definitions is because they already have separate startup and shutdown requirements in place for the program. For example, appendix F of 40 CFR part 75 allows sources to calculate a NO_X emission rate using a "diluent cap" during periods of operation (startup and shutdown) where CO_2 and O_2 are near ambient air levels.[2] As many commenters have noted, these "CEMS data during startup and shutdown" revisions being finalized are necessary to make attainable the CISWI requirement for the standards to "apply at all times" for sources that are otherwise required to measure emissions using CEMS or that opt to measure emissions continually. Further, the EPA does acknowledge that there are instances, such as this one, where consistent regulatory provisions will make compliance demonstrations easier for affected sources and implementing agencies while still maintaining the integrity and goals of the regulation. That is the case here, where multiple programs may require or allow CEMS data for continuous compliance demonstrations.

The commenter also suggested that either using CEMS data corrected to stack oxygen or developing a mass-based standard should be investigated. In essence, though, the revised provisions allow CEMS data to be "corrected to" stack oxygen levels (that is, the numerator and denominator of the oxygen correction are equal, so the correction factor equals 1). Sources must still measure and record concentrations and stack oxygen levels during these periods, and must keep records of periods of CEMS data that are being claimed as periods of startup and shutdown (*See* 40 CFR 60.2175(p) and 40 CFR 60.2740(o)). As many commenters have already noted, the oxygen levels fluctuate widely during startup and shutdown periods, so any basis other than using stack oxygen levels for correction during this period would run into the same type of calculation issue that we are attempting to remedy. Similarly, a mass-based standard for CISWI units would be a significant departure from the format of the existing standards, further complicating compliance demonstrations by the facility and assessment by the implementing agency. In order to develop a calculation-based approach, the EPA would need to have information on the specific materials being fed and resultant emissions for each of the best performing units during startup and shutdown periods. These are data that we do not have and the commenter did not provide any recommendations on an approach that the EPA could consider absent these data. In addition, the EPA did not reopen the specific standards or form of the standards in the proposed rule, and we decline to establish mass-based emission standards for that reason as well. We are not revising the standards, but are revising only the monitoring provisions of the standards to ensure that CEMS data collected are representative of actual emissions during startup and shutdown periods and are not being artificially inflated or influenced due to the 7 percent oxygen correction. In the revisions, these intervals are clearly defined and specific to the unit type to ensure this period is reasonable to ensure safe operation while minimizing emissions.

B. PM Limit for the Waste-Burning Kiln Subcategory

Background: In the January 21, 2015, proposal, the EPA solicited comments on the data set used to determine PM limits for new and existing waste-burning kilns in the February 2013 final rule.

The March 2011 CISWI final rule promulgated PM emissions limits of 6.2 milligrams per dry standard cubic meter (mg/dscm) for existing units, and 2.5 mg/dscm for new units, both corrected to 7 percent oxygen. In an action parallel to the March 21, 2011, final CISWI rule, the EPA promulgated a final rule that identifies the standards and procedures for identifying whether non-hazardous secondary materials (NHSM) are or are not solid waste when used as fuels or ingredients in combustion units. The EPA defines the NHSM that are solid waste under RCRA in the final "Identification of Non-Hazardous Secondary Materials That Are Solid Waste" rulemaking. The RCRA definition of solid waste is integral in defining the CISWI source category. Commercial and industrial units that combust solid waste are subject to standards issued pursuant to CAA section 129, rather than to standards issued pursuant to CAA section 112 that would otherwise be applicable to such units (*e.g.,* boilers, process heaters and cement kilns). Cement kilns combusting solid waste are waste-burning kilns subject to CISWI, not the otherwise applicable Portland Cement NESHAP. Following promulgation of the 2011 CISWI rule, the EPA again analyzed the materials being combusted in the entire national inventory of Portland cement kilns in light of the revisions to the NHSM rule, and made revisions to the CISWI waste-burning kiln inventory. When kilns were added to the inventory and their emissions data considered, the resulting NSPS and EG PM emission limits proposed in the December 2011 reconsideration were less stringent than those established in the March 2011 CISWI final rule.

Following the December 2011 reconsideration proposal, the EPA learned that one of the kilns in the CISWI inventory was no longer burning waste, and another kiln that was not thought to be burning waste materials was doing so. The CISWI waste-burning kiln inventory was revised during the period between proposal and final to reflect these changes, and the database updated to include emissions data for the newly identified unit, as well as some additional test reports obtained for units within the inventory. The EPA calculated the maximum achievable control technology (MACT) floors after making the appropriate revisions to the inventory and the new NSPS and EG PM emission limits were more stringent than those proposed in the December 2011 reconsideration proposal. Table 1 of this preamble tracks the progression of the waste-burning kiln PM limits from the March 2011 final rule through the February 2013 final rule.

Throughout the CISWI rulemaking process from March 2011 through February 2013, the EPA used the same calculation methodology (*i.e.,* the upper prediction limit calculated from a population of individual test runs) to establish the emission limits for waste-burning kilns. However, the data set used in these calculations has changed and grown over this period of time as the agency has revised the CISWI inventory based on information submitted to the agency by the regulated community and new data are submitted. As a result, a petitioner has suggested that the current PM emission data set for waste-burning kilns is robust enough to warrant using 3-run emission test averages as the data population rather than the individual test runs. According to the commenter, using this approach to calculate emission limits would result in PM emission limits that are different than those of the February 2013 CISWI final rule.

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[2] See the "2013 revision of the Part 75 Emissions Policy Manual" accessed August 18, 2015 at *http://www.epa.gov/airmarkets/documents/monitoring/Final-Part75-Policy-Manual-2013-revised-08-27-13.pdf.*

In the context of MACT analyses, as the EPA noted in the January 21, 2015 proposal, emission test averages or individual test run data can be used to determine emissions variability of best performers. We also noted that we typically use individual test runs, but for categories with data from 15[3] or more sources, which would provide at least 45 test runs, we may choose to use test averages. In these larger data sets, the use of test averages are likely to be sufficiently representative of long term performance and variability without the need for use of the individual test runs.

In the January 21, 2015 proposal, the EPA solicited comment on the data set used in the February 2013 final rule, as well as whether this data set warrants a different calculation approach due to its size or other factors. See the memoranda titled "Potential Emission Limits Calculation Analyses for Waste-burning Kilns and Coal ERUs," "Approach for Applying the Upper Prediction Limit to Limited Data Sets," and "Use of the Upper Prediction Limit for Calculating MACT Floors" in the CISWI docket for more details.

Comment: Two commenters supported the use of emission test averages to determine emission standards. One commenter strongly believed that use of test averages is the only valid way to conduct calculations of upper predictive limit (UPL) or other variability analyses because only test averages, and not individual test runs, are statistically independent from one another, as the UPL calculation requires. Both commenters argued that it is crucial that the UPL calculation reflect the actual variability of compliance test results for the best performing kilns that set the floors, and stated that this goal is best accomplished by using stack test results (which are the average of three consecutive test runs) in the UPL calculation, rather than using test runs as individual data points. One commenter noted that the data set for PM emissions from waste-burning kilns is among the largest for any source category or pollutant in the CISWI rule, consisting of 24 stack tests (equivalent to 72 individual test runs) for the pool of three best performers.

One commenter described control measures that Portland Cement NESHAP and waste-burning kilns will need to take to meet the 13.5 mg/dscm limit for existing waste-burning kilns that was discussed, noting that baghouse equipment will still need to be improved at many kilns to meet this limit. The commenter also pointed out that the performance of a baghouse on a kiln is comparable whether it is a Portland Cement NESHAP kiln or a CISWI kiln. The commenter went on to use this discussion and data from the Portland Cement NESHAP analyses to support the 13.5 mg/dscm limit (which equates to 0.075 lb/ton clinker on a production basis, as compared to the existing kiln PM limit of 0.07 lb/ton clinker in the Portland Cement NESHAP) and to demonstrate that the current beyond-the-floor analysis done for the 2013 CISWI final rule is still applicable despite the new PM emission limit.

Response: We agree that the data set for PM for existing waste-burning kilns is sufficiently large to support using stack test averages, as some commenters have supported. For new sources, the EPA realizes that there is a smaller number of data points available when test averages are considered since only the data from the best-performing source are included in the calculation.[4] However, as the EPA has intended within each of the CISWI subcategories, a consistent approach to the emission limit calculation is used for existing and new sources within a subcategory (*e.g.,* upper limit for small remote, UPL for waste-burning kilns). That is, in the case of PM for waste-burning kilns, the UPL using test averages is being used to calculate both existing and new source emission limits.

We also note that, for this particular data set, there are distinct advantages to using this approach. One advantage is that there is a significant amount of test data for the best-performing source. These runs reflect various fuel and waste material firing conditions for the best-performing unit. By splitting the data for the best-performing source into sets of three according to the operational condition (waste or non-waste), each of the resulting averages is more representative of the fuel, waste, and operational variability demonstrated by the other 3-run test averages found in the data set for this source and for the other existing source best performers. In other words, the time periods—and variability in process inputs and operations these periods represent—are approximately equal for each data point in the average data set for existing and new sources. This approach also has the added benefit of a slightly larger time period of operations being represented by the data, since there is one additional average that can be included in the data pool (*i.e.,* no test run data are available, but the average is).

We also reviewed the information submitted by the commenters on the costs and emission improvement requirements existing kilns will need to undertake to meet the revised emission limits, as well as our own assessment of control improvements needed, and agree with the assessment that beyond-the-floor emission standards for waste-burning kiln PM limits are unwarranted. In our analysis, the same kilns that would need improvements for the 2013 PM limits still need to add these improvements to meet the 13.5 mg/dscm standards (as well as the CISWI limits for Cd and Pb, which are not being revised but are also controlled by PM control devices). The technology most likely being used to meet the standards would be fabric filters (baghouses), which is a physical control technology. Information supplied by the industry indicate that many cement kilns will require highly efficient fabric filters to meet the 13.5 mg/dscm standards. Fabric filters do not have a variable component, such as sorbent injection rates, that can be varied easily once the system is designed and the filter media specified. Therefore, unlike other control technologies, the PM removal efficiency of fabric filters does not depend on other factors in the process and control device's performance will essentially be the same regardless of other process inputs. Therefore, the EPA is finalizing the 13.5 mg/dscm and 4.9 mg/dscm emission limits discussed at proposal for existing and new waste-burning kilns, respectively, based on the analysis of emission test average data.

The calculated PM emission limits using the test averages are presented in Table 1 of this preamble for comparison. The calculations used to support the 2015 emission limit values, analyses of impacts and discussion of beyond-the-floor considerations are available in the "Revised Emission Limits and Impacts Analyses for Waste-burning Kilns and

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[3] The 15 test average number discussed in the January 21, 2015 proposal was not a "bright line" value used to establish a possible threshold for when test runs versus test averages may be selected. Rather, this number was an illustrative number that was being discussed as an example in internal EPA discussions at the time the proposal was being written.

[4] Although this data set is smaller than that for existing sources, the EPA does not consider the new source data set to be a small or limited data set.

Coal ERUs" memorandum in the docket to this rulemaking.

TABLE 1—WASTE-BURNING KILN PM EMISSION LIMITS FROM MARCH 2011 FINAL RULE THROUGH 2015 FINAL RECONSIDERATION

Source type (units)	March 2011 final rule	December 2011 proposed rule	February 2013 final rule	2015 Final rule test average-based limits [2]
New Sources (mg/dscm)[1]	2.5	8.9	2.2	4.9
Existing Sources (mg/dscm)[1]	6.2	9.2	4.6	13.5

[1] Corrected to 7 percent oxygen (O_2).
[2] These final limits are the same as those discussed in the January 21, 2015 proposal.

Comment: One commenter disagreed with the proposed approach of using stack test average data, arguing that because the EPA's standards are already set at the floor, and the floor is the minimum stringency permitted by the CAA, the EPA's proposed change is unlawful at Chevron step one.[5] The commenter further argued that the EPA does not give any statutory reasons for its proposed change, and therefore its proposal is unreasonable at Chevron step two. *NRDC* v. *EPA,* No. 12–1321, slip op. at 23 (D.C. Cir. Dec. 23, 2014) ("EPA must 'ground its reasons for action or inaction in the statute.' ") (quoting Util. *Air Regulatory Grp.* v. *EPA,* 134 S. Ct. 2427, 2441 (2014)). The commenter contended that the only reason the EPA gives in support of this change is that the data set for kilns is relatively large and so switching to test averages instead of individual test runs "is expected to make very little difference." The commenter concluded that the EPA's proposed change illustrates that the UPL approach is unlawful and arbitrary because it does not yield reasonable estimates of the "average emission limitation achieved" by the best performing units. An industry commenter asserted that the stack test averages yield reasonable estimates of the average emission limitation achieved by the best performing units, and referred to their original comment submittal to the proposed rule as support. The commenter then repeated that the EPA should use stack test averages in the UPL calculation whenever there are sufficient data to support their use. The commenter concluded that the use of test runs can be justified only when the limited availability of emissions data demands the use of test runs; this is not the case in the CISWI PM limit for kilns.

Response: As discussed earlier, the EPA incorporated considerable new data and moved kilns from the NESHAP to CISWI between the proposed and final CISWI reconsideration concluded in 2013. The inclusion of additional sources and data lead to more stringent standards and the public was not provided an opportunity to comment on those limits and the manner of their calclulation. For this reason, parties petitioned EPA to reconsider those limits consistent with CAA section 307(d)(7)(B), and the EPA granted reconsideration consistent with the statute to provide the public an opportunity to comment. The EPA maintains that its actions in response to the changed circumstances (*i.e.,* new data and sources) and the petitions for reconsideration are consistent with the statute and, for this reason, we reject the commenter's argument that EPA has somehow violated the standard setting provisions of section 112.

Further, we have determined that the data set for existing waste-burning kilns for PM is sufficient to address longer-term performance and variability among the best-performing sources and justifies the use of test average data. While the data set for new waste-burning kilns is smaller in count than that of the existing sources, it is not considered a small data set, and the EPA has concerns about not treating variability consistently between existing and new source emission limits within the same subcategory.

With respect to the commenter's arguments about the UPL calculation methodology, the EPA did not open the UPL calculation methodology for reconsideration, so we are not responding to the commenter's arguments on this issue.

C. FVF for Coal-Burning Energy Recovery Units

Background: In the January 21, 2015, proposal, the EPA requested comments and supporting data regarding the need to establish an FVF for the ERU solids (coal) subcategory. In particular, the EPA requested comments on using stack test data from coal-only periods of operation in our emission limit calculations, and whether the EPA should re-evaluate the NO_X emission limit by using the additional CEMS data provided for the best-performing unit. The preamble to the 2013 final CISWI rule (78 FR 9112, February 7, 2013) explained the methodology used to establish the final emission limits, which relied almost exclusively on direct emissions measurements. A petitioner requested that EPA reconsider the decision not to incorporate fuel variability into the emission limit calculations for coal-fired ERUs based on new information.

Table 2 of this preamble presents a comparison of the 2013 final rule emission limits for existing coal ERUs and the emission limits calculated using all data available (*i.e.,* waste and coal-only modes of operation), FVF calculation techniques, and the additional CEMS data provided by the petitioner.

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[5] *Chevron U.S.A.* v. *NRDC,* 467 U.S. 837 (1984).

TABLE 2—EXISTING COAL ERU EMISSION LIMITS FROM FEBRUARY 2013 FINAL RULE AND BASED ON FVF PLUS ADDITIONAL CEMS DATA

Pollutant (units)	February 2013 final rule emission limit[1]	Final emission limits using additional data and FVF[1]
Cadmium (Cd) (mg/dscm)	0.0095	[2] 0.0017
Hydrogen Chloride (HCl) (ppmv)	13	[3] 58
Mercury (Hg) (mg/dscm)	0.016	[2] 0.013
Lead (Pb) (mg/dscm)	0.14	[3] 0.057
Particulate Matter (PM filterable) (mg/dscm)	160	[2] 130
Nitrogen Oxides (NO_X) (ppmv)	340	[2] 460
Sulfur Dioxide (SO_2) (ppmv)	650	850

[1] All emission limits are expressed as concentrations corrected to 7 percent O_2.

[2] Unable to calculate FVF, final emission limit reflects use of additional data for coal-only mode of operation.

[3] Based on maximum ratio in data set to calculate FVF for final emission limit. If average ratios were used instead, HCl emission limit would be 19 (parts per million by volume) ppmv and Pb would be 0.047 mg/dscm.

Comment: Several commenters supported the revision of these emission limits, claiming that the EPA should account for all sources of emissions variability. Commenters argued that adjustments for fuel variability should be based on worst case conditions so that the floors represent the emission limitations that the best performers can achieve under the worst foreseeable circumstances. They maintained that emissions test data only reflect the pollutant content of a unit's inputs at the time of emissions testing, noting that fuel and solid waste composition vary over time. As an example, commenters referenced HCl data submitted for the top performer, noting that if the HCl limit for existing units remains at 13 ppmv (from the 2013 final CISWI rule), the best performing unit would fail to meet the limit consistently. The commenters further expressed their support for basing the FVF on the maximum ratio of non-paired fuel data with paired fuel data (yielding a limit of 58 ppmv) as opposed to the average ratio (yielding a limit of 19 ppmv), because the HCl data showed the average-based limit was also exceeded several times over an 8-year period. In order to make the HCl limit achievable in practice, the commenters concluded that the EPA must set the final HCl limit to 58 ppmv.

One commenter pointed out that the consideration of fuel variability is of particular importance because a CISWI unit remains a CISWI unit until it ceases to burn waste for at least 6 months. The commenter explained that estimating emission levels achieved when a unit was burning waste and coal does not reflect the level achieved when combusting only coal. Commenters also called attention to the boiler and process heater standards, which account for fuel supply variability, and contended that the EPA should do the same for CIWSI because ERUs would be subject to the boiler standards if they did not combust waste in addition to fossil fuels.

One commenter indicated that the EPA had not properly addressed fuel variability for the SO_2 emission limit. According to the commenter, previously submitted data showed that the 2013 final limit of 650 ppmvd would not be high enough to allow the top performer to comply every day under all operating conditions. In developing the potential limits presented in the proposed reconsideration, the EPA did not develop a FVF for SO_2 because only one fuel data point for sulfur was available to be paired with SO_2 emissions data. The commenter explained that even though only one date from the fuel data matched up with the week of SO_2 CEMS data, the lag time between the fuel sample date and actual combustion in the boiler is typically 4–9 days, so portions of both the August 14 and August 21, 2009, coal shipments would have been burned during the CEMS period from August 23 through August 30, 2009. Therefore, the commenter explained, sulfur data from these two shipments could be paired with the CEMS data, which would make it appropriate to develop a FVF for SO_2, similar to what was done for HCl.

Response: The EPA is finalizing the emission limits for Cd, HCl, Hg, Pb, PM, and NO_X that incorporate a FVF and coal-only mode of operation data and were discussed in the January 21, 2015 proposal. *See* 80 FR at 3023. In addition, the EPA has determined that we have sufficient data to incorporate a FVF into the SO_2 limit in the same manner as the standards for the other section 129 pollutants above.

At proposal, the agency explained our rationale for considering emission limits that incorporate a FVF for fuel-dependent pollutants (*i.e.*, HCl, Pb, Cd, Hg, and SO_2) [*See* 80 FR at 3022] and presented the methodology [See Memo titled "Potential Emission Limits Calculations Analyses for Waste-burning Kilns and Coal ERUs, December 12, 2014] we would use to do so. We also presented the available data. In addition, for Cd, HCl, Hg, Pb, PM and NO_X, the EPA identified the emission limits that incorporate a FVF and were derived from that data and using the proposed methodology. The proposal did not identify a specific SO_2 emission limit that incorporated a FVF because, as explained in the proposal, at that time, the EPA did not believe the data from the best performing units included the information necessary to calculate a FVF for SO_2. *See* 80 FR at 3022; see also Memo titled "Potential Emission Limits Calculations Analyses for Waste-burning Kilns and Coal ERUs, December 12, 2014. The proposal, however, made clear that the rationale for deciding to incorporate a FVF into the emission limits for coal-fired ERUs applied to all fuel-dependent pollutants, including SO_2, and the agency provided the methodology for incorporated a FVF. The comments received demonstrated that the available SO_2 data from the best performing units—the data in the docket at the time of proposal—does in fact include the information required to establish a fuel variability factor. Specifically, the EPA confirms that the data set includes sufficient paired SO_2 data to evaluate the need for a FVF. Thus, all information necessary to address whether a FVF should be incorporated into the SO_2 standard, and to identify the specific SO_2 emission limit incorporating a FVF was available in the docket at the time of proposal. Thus, in this final rule, the EPA has re-evaluated the fuel sulfur data with paired SO_2 data and is incorporating a FVF in the floor calculations for SO_2 using the same methodology that was discussed in the proposal. The resulting SO_2 limit for existing and new coal ERUs is 850 ppmvd.

Comment: One commenter did not support the incorporation of FVFs in determining emission limits, arguing that increasing the floors to account for variability would be unlawful and arbitrary because the UPL methodology used to develop the floors already accounts for emissions variability. According to the commenter, the floors should not be increased further because CAA section 129 directs that standards should be no less stringent than the average emissions achieved by the best performing units. In other words, the commenter explained, a standard must reflect a reasonable estimate of the actual performance of the best units.

The commenter further noted that even if it were lawful to incorporate a FVF at all, the FVF should be based on the average ratio, as opposed to the maximum ratio, because the maximum ratio does not yield a reasonable estimate of the average emissions limitation achieved by the best performing sources, yielding floors less stringent than the statute permits.

Response: The EPA disagrees with the argument that incorporating a FVF in these standards overaccounts for variability. Fuel data provided for the top performing units show that performance for coal-burning ERUs, based solely on the short-term stack test data available for these units, does not adequately reflect the sustained performance and different fuel inputs that are used by the best performing source upon which the standards were based. As stated in response to similar comments submitted on the Boiler NESHAP (*See* EPA–HQ–OAR–2002–0058–3511, excerpt 15, page 111), and consistent with the DC Circuit Court ruling, the EPA is mindful that MACT floors need to reflect achieved performance of the best-performing units, that HAP (or pollutant, for CAA section 129 rules such as CISWI) content of process inputs (raw materials and fuels) should be accounted for in ascertaining the sources' performance as necessary, and that the EPA cannot consider costs in ascertaining the level of the MACT floor. See, *e.g.,* Brick MACT, 479 F. 3d at 880–81, 882–83; *NRDC* v. *EPA,* 489 F. 3d 1364, 1376 (D.C. Cir. 2007) ("Plywood MACT"); see also *Cement Kiln Recycling Coalition* v. *EPA,* 255 F. 3d 855, 861–62 (D.C. Cir. 2001) ("achievability" requirement of CAA section 112 (d)(2) cannot override the requirement that floors be calculated on the basis of what best performers actually achieved). The EPA is also mindful of the need to account for sources' variability (both due to control device performance and variability in inputs) in assessing sources' performance when developing technology-based standards. See, *e.g., Mossville Environmental Action Now* v. *EPA,* 370 F. 3d 1232, 1242 (D.C. Cir. 2004); National Lime I, 627 F. 2d 416, 433–34 (D.C. Cir. 1980). In most cases, the UPL sufficiently accounts for both control device performance and input variability. However, in this case, a review of the data for the best-performing coal-burning ERUs indicated that short-term stack test data alone did not fully account for longer term emissions performance in this case. While fuels combusted within a short term 3-hour test would be expected to be fairly consistent in their contaminant levels, multi-year fuel input data for the best-performing unit show that Hg, Cl, Pb, and sulfur levels can vary significantly between the times the best performing unit is combusting a combination of waste and traditional fuel and the times it is combusting traditional fuels alone, and that there is variability in the pollutant content of the traditional fuel alone as well. In light of this, the EPA believes it is reasonable to incorporate a FVF for this subcategory of CISWI units to better reflect the performance of the best performing coal-burning ERUs.

Regarding the commenter's assertions that the average ratio should be used instead of the maximum ratio in calculating the FVF, we note that, unlike situations present in the Boiler NESHAP, the best-performing units in the coal ERU subcategory (all located at the same facility) are not burning a variety of fuels. These CISWI ERU units burn coal, and periodically an industrial waste generated at the facility. Therefore, there is one fuel and one waste that is input that will influence emissions. This is not the case for the boiler best-performers in the Boiler NESHAP solid fuel subcategory, as these consisted of a "mix of biomass, coal and other solid fossil fuel" data (*See* EPA–HQ–OAR–2002–0058–3836, August 2012). In the boiler rulemaking, the EPA was concerned that this heterogeneous mix of best performer fuel inputs and the use of the maximum ratio would overestimate fuel variability. However, for the CISWI coal ERUs, we are dealing with a single fuel type (coal), and the same concern does not apply. Since CISWI applicability extends for a period beyond the waste-combustion periods, variability in this one fuel influences emissions for a significant portion of the best-performers' operations. Therefore, we have determined that the maximum ratio is appropriate in this case to fully account for the best-performer's variability in fuel inputs.

The FVF accounts for fuel variability between sources using long-term fuel measurement data that represent inherent natural variations in fuel usage at the best performing unit over time. The FVF is used in conjunction with the 99 percent UPL to characterize long-term variability due to technological controls and fuel characteristics. The results are MACT floors that reasonably estimate the performance over time of the best performing sources (there are three identical units at one facility that are best performers for this subcategory of unit, with only one additional unit that may be in this subcategory). These calculations are described in more detail in the "Revised Emission Limits and Impacts Analyses for Waste-burning Kilns and Coal ERUs" memorandum found in the docket to this rulemaking.

For these reasons, the EPA is adopting the revised emission limits for coal ERUs discussed in the January 21, 2015, proposal, and the agency is also incorporating a FVF into the SO_2 limit as discussed above.

D. Definition of "Kiln"

Background: In the January 21, 2015, notice, the EPA requested comment on its proposal to revise the definition of "kiln" and proposal to add definitions of "in-line raw mill" and "in-line coal mill" to further clarify the boundaries of the waste-burning kiln. Because the in-line raw mill and in-line coal mill are part of the kiln, the kiln emission limits also apply to the exhaust of the in-line raw mill and in-line coal mill. For more background on this issue, the EPA discussed at length in the preamble to the proposed Portland Cement NESHAP a potential regulatory regime to cover situations where a portion of the kiln exhaust is ducted to the coal mill. See 77 FR 42383–85; see also the regulatory text at 77 FR 42398, 42402–06, 42408–09.

For waste-burning kilns, the EPA proposed language in the definition of "kiln" to make it consistent with that of the Portland Cement NESHAP. The terms "in-line raw mill" and "in-line coal mill" were proposed to be included in the definition, and, therefore, were proposed to be added to the definitions within the CISWI rule.

In addition to the proposed definitional amendments in the January 21, 2015, notice, the EPA proposed a compliance demonstration and ongoing monitoring method for waste-burning kilns that combine emission streams from the in-line raw mill and in-line coal mill and exhaust through multiple stacks. The EPA is finalizing the proposed approach with some minor revisions to address comments as discussed below. The final rule will allow sources to measure pollutant concentrations and flows from each of the stacks (*i.e.,* kiln, alkali bypass, and in-line coal mill, as applicable) and calculate a flow-weighted average kiln stack concentration that must be met in order to be in compliance with the CISWI waste-burning kiln emission limits. These provisions are modeled upon similar provisions and equations found in the Portland Cement NESHAP, and should streamline compliance demonstrations for waste-burning kilns that combine streams prior to discharge to the atmosphere through one or more stacks. The proposed calculation method and measurement location options are found in 40 CFR 60.2145 and 40 CFR 60.2710. The EPA requested comment on the definitional and calculation method changes for demonstrating compliance for waste-burning kilns that combine streams prior to discharge to the atmosphere through one or more stacks.

Comment: Although there were no specific comments on the revised definition of "kiln" or on the addition of the definitions of "in-line raw mill" and "in-line coal mill," one commenter expressed the need to change monitoring and compliance requirements for alkali bypass and/or in-line coal mill to be consistent with the Portland Cement NESHAP. The commenter contended the use of CEMS and the PM CPMS for either an alkali bypass or an in-line coal mill is unnecessary, as they represent a relatively minor part of the overall kiln emissions and their emissions will vary directionally with the main kiln stack concentrations. Therefore, the commenter suggested that monitoring the main kiln stack alone can provide an indication of overall emissions and compliance. The commenter stated that the appropriate monitoring and compliance requirements have already been addressed in the Portland Cement NESHAP rule and requested that the EPA adopt a similar approach for the CISWI standards. The commenter also suggested that the EPA clarify the level of testing and monitoring that applies to either an alkali by-pass or an in-line coal mill.

Response: To provide additional consistency between CISWI and the Portland Cement NESHAP, the EPA is adding clarifying language in the final rule that makes the monitoring requirements for waste-burning kilns consistent with those in the Portland Cement NESHAP. Specifically, we are not requiring that CEMS or PM CPMS need to be installed on separate alkali bypass or in-line coal mill stacks. Instead, as is the case with the Portland Cement NESHAP, the results of the initial and subsequent performance test for the alkali bypass and in-line coal mill stacks can be used to determine the combined emissions to demonstrate compliance with the relevant emissions limit. However, unlike the Portland Cement NESHAP, the performance test must be conducted on an annual basis (between 11 and 13 calendar months following the previous performance test) to keep the testing schedule for these stacks consistent with the CISWI rule's annual performance testing requirements.

V. Technical Corrections and Clarifications

In the January 21, 2015, notice, the EPA proposed to correct minor typographical errors and clarify provisions of the final rule that may have been unclear. The EPA is finalizing these corrections, which are summarized in this section of the preamble. There were some comments received on these clarifications. These comments, and responses to them, are found in the "2013 CISWI Rule Reconsideration Response to Comments."

A. 2000 CISWI New Source Applicability Clarification for Incinerators and Air Curtain Incinerators

Following promulgation of the February 2013 CISWI final rule, the EPA received questions regarding the continued applicability of the 2000 CISWI NSPS for units that are subject to the 2000 CISWI NSPS as they are transitioned from the 2000 NSPS to the February 2013 EG with which they will eventually be required to comply. The 2000 CISWI NSPS are the same as the 2000 CISWI EG and limited in applicability to the incinerator subcategory and air curtain incinerators so only these types of CISWI units being regulated in the February 2013 CISWI final rules are affected by this applicability issue. The EPA intended, consistent with the statute and our stated intent (see 76 FR 15711, March 21, 2011), to continue to regulate these units as "new" sources under the 2000 NSPS, and then regulate them as "existing" sources under the 2013 EG once these units were covered under an approved state plan or federal plan that implements the February 2013 CISWI final EG. The language in the February 7, 2013, NSPS at 40 CFR 60.2105 and the title of Table 1 to 40 CFR part 60, subpart CCCC make the EPA's intent to do so evident. However, the applicability section in 40 CFR 60.2015 omitted the applicability provisions for incinerators and air curtain incinerators that are subject to the 2000 CISWI NSPS. In this final rule, the EPA is finalizing proposed additional language in 40 CFR 60.2015(a) and 40 CFR 60.2105(b) that clarifies that these incinerators and air curtain incinerators remain "new" units regulated under the 2000 NSPS until such time that an approved state plan or federal plan implements the February 2013 EG for those units, at which time such units will be subject to the 2013 EG to the extent those limits are more stringent than the 2000 CISWI NSPS limits, which will continue to apply if they are more stringent.

B. Typographical Errors and Corrections

The following items are typographical errors in the final rule that we are correcting in this final action:

- References in 40 CFR 60.2020(e), 60.2020(f), 60.2555(e), and 60.2555(f) were changed from ". . . paragraphs (e)(1) through (3) . . ." to ". . . paragraphs (e)(1) through (4) . . .".
- Restructured 40 CFR 60.2060 to add paragraph (b) that clarifies waste management plan submittal timeline for CISWI units that commence reconstruction or modification after August 7, 2013.
- References in 40 CFR 60.2020(i) and 60.2245 were revised to include 40 CFR 60.2242 in addition to 40 CFR 60.2245 through 60.2260 (*i.e.,* clarifies that air curtain incinerators burning wood waste, clean lumber, and/or yard waste must obtain title V permits).
- References in 40 CFR 60.2555(i) and 60.2810 were revised to include 40 CFR 60.2805 in addition to 40 CFR 60.2810 through 60.2870 (*i.e.,* clarifies that air curtain incinerators burning wood waste, clean lumber, and/or yard waste must obtain title V permits).
- References in 40 CFR 60.2110(i)(2)(i)(D) and 40 CFR 60.2675(i)(2)(i)(D) were changed from ". . . paragraphs (i)(2)(i) through (iv) . . ." to ". . . paragraphs (i)(2)(i)(A) through (i)(2)(i)(C) . . .".
- Two references in the definitions of terms for Equation 3 in 40 CFR 60.2110(i)(2)(iv) were revised. For the 'z' term, "(2)(a)" was corrected to "(2)(i)", and for the 'R' term, "Equation 3" was corrected to "Equation 2".
- Two references in the definitions of terms for Equation 3 in 40 CFR 60.2675(i)(2)(iv) were revised. For the 'z' term, "(2)(a)" was corrected to "(2)(i)", and for the 'R' term, "Equation 3" was corrected to "Equation 2".
- The language in 40 CFR 60.2140(c) and 60.2705(c) were revised to include the phrase "commence or recommence

combusting" to be parallel to the same terminology in 40 CFR 60.2140(b) and 60.2705(b), respectively.

- Extra spaces were removed from 40 CFR 60.2145(v) and 60.2710(v).
- The reference in 40 CFR 60.2145(w)(1) was changed from "§ 60.2675" to "§ 60.2140".
- The references in 40 CFR 60.2145(x)(1) were changed from ". . . § 60.2145(l) and (x)(1)(i) through (iii) . . ." to ". . . paragraphs (l) and (x)(1)(i) through (x)(1)(iii) . . ."
- The references in 40 CFR 60.2710(x)(1) were changed from ". . .§ 60.2710(l) and (x)(1)(i) through (iii). . ." to ". . . paragraphs (l) and (x)(1)(i) through (x)(1)(iii). . ."
- Language in 40 CFR 60.2145(x)(1)(iii), 60.2165(r)(1)(iii), 60.2710(x)(1)(iii) and 60.2730(r)(1)(iii) was revised to clarify the PM continuous parameter monitoring system (CPMS) detection limit. The phrase "of no greater than" was changed to "increments no greater than".
- Provisions for PM CPMS in both subparts were revised to also clarify the output signals from digital monitoring devices and remove "lb/Mmbtu" typographical errors.
- The reference in 40 CFR 60.2165(q)(1) was changed from "§ 60.2675" to "§ 60.2140".
- Text in 40 CFR 60.2165(q)(3) was corrected from ". . .paragraph (q)(4) or this section . . ." to ". . . paragraph (q)(4) of this section . . .".
- The title of 40 CFR part 60, subpart CCCC Table 1 was revised to clarify that these emission limits apply to incinerators that were subject to the 2000 CISWI rule provisions.
- The dates in paragraphs (a)(1) and (2) of 40 CFR 60.2535 from the 2000 CISWI rule were omitted in the current CFR version of the rule, and have been reinserted.
- Added text in 40 CFR 60.2525(b) and 60.2535(b) to clarify applicability for incinerators and air curtain incinerators that were reconstructed or modified on or after June 1, 2001, but no later than August 7, 2013.
- Revised the language of 40 CFR 60.2550(b) to reflect the August 7, 2013 date for purposes of applicability with 40 CFR part 60, subpart CCCC.
- The text "over 10 MMBtu/hr but less than 250 MMBtu/hr annual average heat input rates" was added to 40 CFR 60.2730(m) for clarification and consistency.
- The definition of chemical recovery unit in 40 CFR 60.2265 was revised to be consistent with the definition provided in 40 CFR 60.2875. The following text was added: "A chemical recovery unit is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart."
- Clarifying language was added to the HCl row of 40 CFR part 60, subpart DDDD Table 8. Compliance method text was changed from ". . . if a wet scrubber is not used" to ". . . if a wet scrubber or dry scrubber is not used."
- Text in 40 CFR 60.2165(o) was corrected from ". . . you must use a continuous automated sampling system . . ." to ". . . you may substitute use of a continuous automated sampling system for the carbon monoxide annual performance test."
- Revise the definition of "Oxygen trim system" to include draft controller and to clarify that it is a system that maintains the desired excess air level over the operating load range.
- Revise the definition of "Reconstruction" in both subparts to reflect the correct criterion that reconstruction begins on or after August 7, 2013.
- Renumbered equations in 40 CFR part 60, subpart DDDD to be in sequence within the subpart instead of being a continuation with 40 CFR part 60, subpart CCCC.
- Revised paragraphs 40 CFR 60.2030(c), 60.2210(h), 60.2220(d), 60.2235, 60.2770(h), 60.2780(d) and 60.2795 to reflect the most recent electronic reporting guidance available and to further clarify reporting requirements.
- Revised paragraphs 40 CFR 60.2145(j)(1) and 60.2710(j)(1) to reflect the most recent guidance available for HCl CEMS installed and certified in accordance to Performance Specification 15 or Performance Specification 18.
- Table footnotes were converted from alphabetical to numeric format.
- Deleted inadvertent footnote references to the following: Dioxin/furan TEQ and TMB rows of 40 CFR part 60, subpart CCCC Table 8; Dioxin/furan TMB row and Pb row of 40 CFR part 60, subpart DDDD Table 7; Dioxin/furan row of 40 CFR part 60, subpart DDDD Table 8; and dioxin/furan row of 40 CFR part 60, subpart DDDD Table 9.

C. Clarifications

Since publication of the February 7, 2013, final CISWI rule, the EPA has received stakeholder questions and requests for clarification on certain rule provisions. We are not finalizing any regulatory language changes for the following items, but are providing some clarification to these questions. Furthermore, comments received on these clarifications and responses to these comments are found in the "Response to Comments on the 2015 CISWI Reconsideration" document found in the docket:

- Mass balance as operating limits for units without certain control devices—A stakeholder has asked for clarification on whether a mass balance could be used as an operating parameter, and whether this must be measured as a 30-day rolling average instead of taking a monthly sample. Furthermore, the stakeholder also asked whether the material balance allows them to waive annual stack testing. The EPA clarifies that mass balance operating parameters do not replace annual stack testing. Stack testing and operating parameters work in tandem to ensure ongoing compliance with the standards. We do, however, accept that mass balance could be an allowable operating parameter in cases where no control device is needed to meet the pollutant's specific emission limit applicable to the unit, provided the petition for the operating parameter limits meets the requirements specified in 40 CFR 60.2115 and 40 CFR 60.2680. We also point out that these requirements also allow any source to request a different averaging time that is appropriate for the source and operating parameter.
- Clarification on who the "EPA Administrator" is and whom to contact for requests for averaging times, qualifying facility notifications, etc. We have received questions on how to contact the Administrator to submit notifications, reports and requests. The contact information is given in the General Provisions, under 40 CFR 60.4, and has addresses listed by EPA Regional Offices.

VI. Environmental, Energy and Economic Impacts

This action finalizes the proposed provisions and makes technical and clarifying corrections, but does not cause substantive changes to the impacts on the environment, energy generation and usage, and economic factors for affected sources from the February 7, 2013, final CISWI rule (78 FR 9112). The number of sources requiring improved emission control performance is the same as estimated in the final 2013 rule. While the emission limits have been relaxed slightly for PM in the waste-burning kilns, the assumed controls required to meet the final standards are still the same as those estimated for the final 2013 rule. That is, waste-burning kilns that would require additional controls to meet the final 2013 rule's PM and metals emission limits will still require those control improvements to meet the limits being finalized in this action. The main difference is an increased margin of compliance for these units, as well as a PM limit that is very consistent with the non-waste burning (Portland Cement NESHAP) PM emission limits, thereby streamlining compliance. For the coal-fired ERU subcategory, certain emission limits are relaxed while others have been made more stringent. The net result in emissions reductions are negligible, however, and there are no changes in the control cost estimates for units in this subcategory. As with the waste-burning kilns, the main difference for the coal ERUs is that there is a somewhat greater margin of compliance available in the standards being finalized, and thus, ensuring that the best performing units may be able to demonstrate sustained compliance with the MACT standards in multiple modes of operation (waste and non-waste modes).

Taken together, the revised emission limits being finalized in this action could result in allowable emission estimates, primarily in PM, that are greater than those assumed for the 2013 final rule by about 297 tpy. In other words, there could potentially be 297 fewer tpy of PM emission reductions as a result of this final rule when compared to the 2013 final rule's estimated emission reductions. We have estimated these emission impacts in the memorandum "Revised Emission Limits and Impacts Analyses for Waste-burning Kilns and Coal ERUs" available in the docket. We have not revised the regulatory impacts assessment prepared for the 2013 final rule since the expected emissions control costs are unchanged and the change in estimated emission reductions are relatively minor when compared to the 34,771 tpy overall emission reductions estimated for the February 7, 2013, final rule (*See* 78 FR 9132).

VII. Statutory and Executive Order Reviews

Additional information about these statues and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was, therefore, not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations (40 CFR part 60, subpart CCCC and 40 CFR part 60, subpart DDDD) and has assigned OMB control number 2060–0664 for subpart CCCC and OMB control number 2060–0662 for subpart DDDD. This action is believed to result in no changes to the information collection requirements of the February 2013 final CISWI rule, so that the information collection estimate of project cost and hour burden from the final CISWI rule have not been revised.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden, or otherwise has a positive economic effect on the small entities subject to the rule. This final rule will not impose any new requirements on any entities because it does not impose any additional regulatory requirements relative to those specified in the February 2013 final CISWI rule. The February 2013 final CISWI rule was certified as not having a significant economic impact on a substantial number of small entities. We have therefore concluded that this action will have no net regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175. The EPA is not aware of any CISWI in Indian country or owned or operated by Indian tribal governments. The CISWI aspects of this rule may, however, invoke minor indirect tribal implications to the extent that entities generating solid wastes on tribal lands could be affected. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This action does not involve technical standards.

This action is not finalizing any new incorporation by reference material, so therefore this action is not making any amendments to the incorporations by reference found in 40 CFR 60.17. The incorporation by reference of this document was already approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 for § 60.14, effective February 7, 2013. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes the human health or environmental risk addressed by this action will *not* have potential disproportionately high and adverse human health or environmental effects on minority, low-income, or indigenous populations. It does not affect the level of protection provided to human health or the environment. The final CISWI rule will reduce emissions of all the listed toxics emitted from this source, thereby helping to further ensure against any disproportionately high and adverse human health or environmental effects on minority, low-income, or indigenous populations.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to House of Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 60

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Incorporation by reference.

Dated: May 5, 2016.

Gina McCarthy,

Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency is amending title 40, chapter I, of the Code of Federal Regulations as follows:

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

■ 1. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

■ 2. Part 60 is amended by revising subpart CCCC to read as follows:

Subpart CCCC—Standards of Performance for Commercial and Industrial Solid Waste Incineration Units

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Table 7 to Subpart CCCC of Part 60—Emission Limitations for Waste-burning Kilns That Commenced Construction After June 4, 2010, or Reconstruction or Modification After August 7, 2013

Table 8 to Subpart CCCC of Part 60—Emission Limitations for Small, Remote Incinerators That Commenced Construction After June 4, 2010, or That Commenced Reconstruction or Modification After August 7, 2013

Subpart CCCC—Standards of Performance for Commercial and Industrial Solid Waste Incineration Units

Introduction

§ 60.2000 What does this subpart do?

This subpart establishes new source performance standards for commercial and industrial solid waste incineration (CISWI) units.

§ 60.2005 When does this subpart become effective?

This subpart takes effect on August 7, 2013. Some of the requirements in this subpart apply to planning the CISWI unit (*i.e.*, the preconstruction requirements in §§ 60.2045 and 60.2050). Other requirements such as the emission limitations and operating limits apply after the CISWI unit begins operation.

Applicability

§ 60.2010 Does this subpart apply to my incineration unit?

Yes, if your incineration unit meets all the requirements specified in paragraphs (a) through (c) of this section:

(a) Your incineration unit is a new incineration unit as defined in § 60.2015;

(b) Your incineration unit is a CISWI unit as defined in § 60.2265; and

(c) Your incineration unit is not exempt under § 60.2020.

§ 60.2015 What is a new incineration unit?

(a) A new incineration unit is an incineration unit that meets any of the criteria specified in paragraphs (a)(1) through (3) of this section:

(1) A CISWI unit that commenced construction after June 4, 2010;

(2) A CISWI unit that commenced reconstruction or modification after August 7, 2013; and

(3) Incinerators and air curtain incinerators, as defined in this subpart, that commenced construction after November 30, 1999, but no later than June 4, 2010, or that commenced reconstruction or modification on or after June 1, 2001, but no later than August 7, 2013, are considered new incineration units and remain subject to the applicable requirements of this subpart until the units become subject to the requirements of an approved state plan or federal plan that implements subpart DDDD of this part (Emission Guidelines and Compliance Times for Commercial and Industrial Solid Waste Incineration Units).

(b) This subpart does not affect your CISWI unit if you make physical or operational changes to your incineration unit primarily to comply with subpart DDDD of this part (Emission Guidelines and Compliance Times for Commercial and Industrial Solid Waste Incineration Units). Such changes do not qualify as reconstruction or modification under this subpart.

§ 60.2020 What combustion units are exempt from this subpart?

This subpart exempts the types of units described in paragraphs (a), (c) through (i), and (n) of this section, but some units are required to provide notifications. Air curtain incinerators are exempt from the requirements in this subpart except for the provisions in §§ 60.2242, 60.2250, and 60.2260.

(a) *Pathological waste incineration units.* Incineration units burning 90 percent or more by weight (on a calendar quarter basis and excluding the weight of auxiliary fuel and combustion air) of pathological waste, low-level radioactive waste, and/or chemotherapeutic waste as defined in § 60.2265 are not subject to this subpart if you meet the two requirements specified in paragraphs (a)(1) and (2) of this section:

(1) Notify the Administrator that the unit meets these criteria; and

(2) Keep records on a calendar quarter basis of the weight of pathological waste, low-level radioactive waste, and/or chemotherapeutic waste burned, and the weight of all other fuels and wastes burned in the unit.

(b) [Reserved]

(c) *Municipal waste combustion units.* Incineration units that are subject to subpart Ea of this part (Standards of Performance for Municipal Waste Combustors); subpart Eb of this part (Standards of Performance for Large Municipal Waste Combustors); subpart Cb of this part (Emission Guidelines and Compliance Time for Large Municipal Combustors); subpart AAAA of this part (Standards of Performance for Small Municipal Waste Combustion Units); or subpart BBBB of this part (Emission Guidelines for Small Municipal Waste Combustion Units).

(d) *Medical waste incineration units.* Incineration units regulated under subpart Ec of this part (Standards of Performance for Hospital/Medical/Infectious Waste Incinerators for Which Construction is Commenced After June 20, 1996) or subpart Ce of this part (Emission Guidelines and Compliance Times for Hospital/Medical/Infectious Waste Incinerators).

(e) *Small power production facilities.* Units that meet the three requirements specified in paragraphs (e)(1) through (4) of this section:

(1) The unit qualifies as a small power-production facility under section 3(17)(C) of the Federal Power Act (16 U.S.C. 796(17)(C));

(2) The unit burns homogeneous waste (not including refuse-derived fuel) to produce electricity;

(3) You submit documentation to the Administrator notifying the EPA that the qualifying small power production facility is combusting homogenous waste; and

(4) You maintain the records specified in § 60.2175(w).

(f) *Cogeneration facilities.* Units that meet the three requirements specified in paragraphs (f)(1) through (4) of this section:

(1) The unit qualifies as a cogeneration facility under section 3(18)(B) of the Federal Power Act (16 U.S.C. 796(18)(B));

(2) The unit burns homogeneous waste (not including refuse-derived fuel) to produce electricity and steam or other forms of energy used for industrial, commercial, heating, or cooling purposes;

(3) You submit documentation to the Administrator notifying the Agency that

the qualifying cogeneration facility is combusting homogenous waste; and

(4) You maintain the records specified in § 60.2175(x).

(g) *Hazardous waste combustion units.* Units for which you are required to get a permit under section 3005 of the Solid Waste Disposal Act.

(h) *Materials recovery units.* Units that combust waste for the primary purpose of recovering metals, such as primary and secondary smelters.

(i) *Air curtain incinerators.* Air curtain incinerators that burn only the materials listed in paragraphs (i)(1) through (3) of this section are only required to meet the requirements under § 60.2242 and under "Air Curtain Incinerators" (§§ 60.2245 through 60.2260):

(1) 100 percent wood waste;

(2) 100 percent clean lumber; and

(3) 100 percent mixture of only wood waste, clean lumber, and/or yard waste.

(j)–(l) [Reserved]

(m) *Sewage treatment plants.* Incineration units regulated under subpart O of this part (Standards of Performance for Sewage Treatment Plants).

(n) *Sewage sludge incineration units.* Incineration units combusting sewage sludge for the purpose of reducing the volume of the sewage sludge by removing combustible matter that are subject to subpart LLLL of this part (Standards of Performance for New Sewage Sludge Incineration Units) or subpart MMMM of this part (Emission Guidelines and Compliance Times for Existing Sewage Sludge Incineration Units).

(o) *Other solid waste incineration units.* Incineration units that are subject to subpart EEEE of this part (Standards of Performance for Other Solid Waste Incineration Units for Which Construction is Commenced After December 9, 2004, or for Which Modification or Reconstruction is Commenced on or After June 16, 2006) or subpart FFFF of this part (Emission Guidelines and Compliance Times for Other Solid Waste Incineration Units That Commenced Construction On or Before December 9, 2004).

§ 60.2030 Who implements and enforces this subpart?

(a) This subpart can be implemented and enforced by the U.S. Environmental Protection Agency (EPA), or a delegated authority such as your state, local, or tribal agency. If the EPA Administrator has delegated authority to your state, local, or tribal agency, then that agency (as well as EPA) has the authority to implement and enforce this subpart. You should contact your EPA Regional Office to find out if this subpart is delegated to your state, local, or tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to a state, local, or tribal agency, the authorities contained in paragraph (c) of this section are retained by the EPA Administrator and are not transferred to the state, local, or tribal agency.

(c) The authorities that will not be delegated to state, local, or tribal agencies are specified in paragraphs (c)(1) through (4) and (c)(6) through (11) of this section:

(1) Approval of alternatives to the emission limitations in table 1 of this subpart and operating limits established under § 60.2110;

(2) Approval of major alternatives to test methods;

(3) Approval of major alternatives to monitoring;

(4) Approval of major alternatives to recordkeeping and reporting;

(5) [Reserved]

(6) The requirements in § 60.2115;

(7) The requirements in § 60.2100(b)(2);

(8) Approval of alternative opacity emission limits in § 60.2105 under § 60.11(e)(6) through (8);

(9) Performance test and data reduction waivers under § 60.2125(j), § 60.8(b)(4) and (5);

(10) Determination of whether a qualifying small power production facility or cogeneration facility under § 60.2020(e) or (f) is combusting homogenous waste; and

(11) Approval of an alternative to any electronic reporting to the EPA required by this subpart.

§ 60.2035 How are these new source performance standards structured?

These new source performance standards contain the eleven major components listed in paragraphs (a) through (k) of this section:

(a) Preconstruction siting analysis;

(b) Waste management plan;

(c) Operator training and qualification;

(d) Emission limitations and operating limits;

(e) Performance testing;

(f) Initial compliance requirements;

(g) Continuous compliance requirements;

(h) Monitoring;

(i) Recordkeeping and reporting;

(j) Definitions; and

(k) Tables.

§ 60.2040 Do all eleven components of these new source performance standards apply at the same time?

No. You must meet the preconstruction siting analysis and waste management plan requirements before you commence construction of the CISWI unit. The operator training and qualification, emission limitations, operating limits, performance testing and compliance, monitoring, and most recordkeeping and reporting requirements are met after the CISWI unit begins operation.

Preconstruction Siting Analysis

§ 60.2045 Who must prepare a siting analysis?

(a) You must prepare a siting analysis if you plan to commence construction of an incinerator after December 1, 2000.

(b) You must prepare a siting analysis for CISWI units that commenced construction after June 4, 2010, or that commenced reconstruction or modification after August 7, 2013.

(c) You must prepare a siting analysis if you are required to submit an initial application for a construction permit under 40 CFR part 51, subpart I, or 40 CFR part 52, as applicable, for the reconstruction or modification of your CISWI unit.

§ 60.2050 What is a siting analysis?

(a) The siting analysis must consider air pollution control alternatives that minimize, on a site-specific basis, to the maximum extent practicable, potential risks to public health or the environment. In considering such alternatives, the analysis may consider costs, energy impacts, nonair environmental impacts, or any other factors related to the practicability of the alternatives.

(b) Analyses of your CISWI unit's impacts that are prepared to comply with state, local, or other federal regulatory requirements may be used to satisfy the requirements of this section, provided they include the consideration of air pollution control alternatives specified in paragraph (a) of this section.

(c) You must complete and submit the siting requirements of this section as required under § 60.2190(c) prior to commencing construction.

Waste Management Plan

§ 60.2055 What is a waste management plan?

A waste management plan is a written plan that identifies both the feasibility and the methods used to reduce or separate certain components of solid waste from the waste stream in order to reduce or eliminate toxic emissions from incinerated waste.

§ 60.2060 When must I submit my waste management plan?

(a) You must submit a waste management plan prior to commencing construction.

(b) For CISWI units that commence reconstruction or modification after August 7, 2013, you must submit a waste management plan prior to the commencement of modification or reconstruction.

§ 60.2065 What should I include in my waste management plan?

A waste management plan must include consideration of the reduction or separation of waste-stream elements such as paper, cardboard, plastics, glass, batteries, or metals; or the use of recyclable materials. The plan must identify any additional waste management measures and implement those measures the source considers practical and feasible, considering the effectiveness of waste management measures already in place, the costs of additional measures, the emissions reductions expected to be achieved, and any other environmental or energy impacts they might have.

Operator Training and Qualification

§ 60.2070 What are the operator training and qualification requirements?

(a) No CISWI unit can be operated unless a fully trained and qualified CISWI unit operator is accessible, either at the facility or can be at the facility within 1 hour. The trained and qualified CISWI unit operator may operate the CISWI unit directly or be the direct supervisor of one or more other plant personnel who operate the unit. If all qualified CISWI unit operators are temporarily not accessible, you must follow the procedures in § 60.2100.

(b) Operator training and qualification must be obtained through a state-approved program or by completing the requirements included in paragraph (c) of this section.

(c) Training must be obtained by completing an incinerator operator training course that includes, at a minimum, the three elements described in paragraphs (c)(1) through (3) of this section:

(1) Training on the eleven subjects listed in paragraphs (c)(1)(i) through (xi) of this section;

(i) Environmental concerns, including types of emissions;

(ii) Basic combustion principles, including products of combustion;

(iii) Operation of the specific type of incinerator to be used by the operator, including proper startup, waste charging, and shutdown procedures;

(iv) Combustion controls and monitoring;

(v) Operation of air pollution control equipment and factors affecting performance (if applicable);

(vi) Inspection and maintenance of the incinerator and air pollution control devices;

(vii) Actions to prevent and correct malfunctions or to prevent conditions that may lead to malfunctions;

(viii) Bottom and fly ash characteristics and handling procedures;

(ix) Applicable federal, state, and local regulations, including Occupational Safety and Health Administration workplace standards;

(x) Pollution prevention; and

(xi) Waste management practices.

(2) An examination designed and administered by the instructor.

(3) Written material covering the training course topics that may serve as reference material following completion of the course.

§ 60.2075 When must the operator training course be completed?

The operator training course must be completed by the later of the three dates specified in paragraphs (a) through (c) of this section:

(a) Six months after your CISWI unit startup;

(b) December 3, 2001; and

(c) The date before an employee assumes responsibility for operating the CISWI unit or assumes responsibility for supervising the operation of the CISWI unit.

§ 60.2080 How do I obtain my operator qualification?

(a) You must obtain operator qualification by completing a training course that satisfies the criteria under § 60.2070(b).

(b) Qualification is valid from the date on which the training course is completed and the operator successfully passes the examination required under § 60.2070(c)(2).

§ 60.2085 How do I maintain my operator qualification?

To maintain qualification, you must complete an annual review or refresher course covering, at a minimum, the five topics described in paragraphs (a) through (e) of this section:

(a) Update of regulations;

(b) Incinerator operation, including startup and shutdown procedures, waste charging, and ash handling;

(c) Inspection and maintenance;

(d) Prevention and correction of malfunctions or conditions that may lead to malfunction; and

(e) Discussion of operating problems encountered by attendees.

§ 60.2090 How do I renew my lapsed operator qualification?

You must renew a lapsed operator qualification by one of the two methods specified in paragraphs (a) and (b) of this section:

(a) For a lapse of less than 3 years, you must complete a standard annual refresher course described in § 60.2085; and

(b) For a lapse of 3 years or more, you must repeat the initial qualification requirements in § 60.2080(a).

§ 60.2095 What site-specific documentation is required?

(a) Documentation must be available at the facility and readily accessible for all CISWI unit operators that addresses the ten topics described in paragraphs (a)(1) through (10) of this section. You must maintain this information and the training records required by paragraph (c) of this section in a manner that they can be readily accessed and are suitable for inspection upon request:

(1) Summary of the applicable standards under this subpart;

(2) Procedures for receiving, handling, and charging waste;

(3) Incinerator startup, shutdown, and malfunction procedures;

(4) Procedures for maintaining proper combustion air supply levels;

(5) Procedures for operating the incinerator and associated air pollution control systems within the standards established under this subpart;

(6) Monitoring procedures for demonstrating compliance with the incinerator operating limits;

(7) Reporting and recordkeeping procedures;

(8) The waste management plan required under §§ 60.2055 through 60.2065;

(9) Procedures for handling ash; and

(10) A list of the wastes burned during the performance test.

(b) You must establish a program for reviewing the information listed in paragraph (a) of this section with each incinerator operator:

(1) The initial review of the information listed in paragraph (a) of this section must be conducted within 6 months after the effective date of this subpart or prior to an employee's assumption of responsibilities for operation of the CISWI unit, whichever date is later; and

(2) Subsequent annual reviews of the information listed in paragraph (a) of this section must be conducted not later than 12 months following the previous review.

(c) You must also maintain the information specified in paragraphs (c)(1) through (3) of this section:

(1) Records showing the names of CISWI unit operators who have completed review of the information in § 60.2095(a) as required by § 60.2095(b), including the date of the initial review and all subsequent annual reviews;

(2) Records showing the names of the CISWI operators who have completed the operator training requirements under § 60.2070, met the criteria for qualification under § 60.2080, and maintained or renewed their qualification under § 60.2085 or § 60.2090. Records must include documentation of training, the dates of the initial and refresher training, and the dates of their qualification and all subsequent renewals of such qualifications; and

(3) For each qualified operator, the phone and/or pager number at which they can be reached during operating hours.

§ 60.2100 What if all the qualified operators are temporarily not accessible?

If all qualified operators are temporarily not accessible (*i.e.*, not at the facility and not able to be at the facility within 1 hour), you must meet one of the two criteria specified in paragraphs (a) and (b) of this section, depending on the length of time that a qualified operator is not accessible:

(a) When all qualified operators are not accessible for more than 8 hours, but less than 2 weeks, the CISWI unit may be operated by other plant personnel familiar with the operation of the CISWI unit who have completed a review of the information specified in § 60.2095(a) within the past 12 months. However, you must record the period when all qualified operators were not accessible and include this deviation in the annual report as specified under § 60.2210; and

(b) When all qualified operators are not accessible for 2 weeks or more, you must take the two actions that are described in paragraphs (b)(1) and (2) of this section:

(1) Notify the Administrator of this deviation in writing within 10 days. In the notice, state what caused this deviation, what you are doing to ensure that a qualified operator is accessible, and when you anticipate that a qualified operator will be accessible; and

(2) Submit a status report to the Administrator every 4 weeks outlining what you are doing to ensure that a qualified operator is accessible, stating when you anticipate that a qualified operator will be accessible and requesting approval from the Administrator to continue operation of the CISWI unit. You must submit the first status report 4 weeks after you notify the Administrator of the deviation under paragraph (b)(1) of this section. If the Administrator notifies you that your request to continue operation of the CISWI unit is disapproved, the CISWI unit may continue operation for 90 days, then must cease operation. Operation of the unit may resume if you meet the two requirements in paragraphs (b)(2)(i) and (ii) of this section:

(i) A qualified operator is accessible as required under § 60.2070(a); and

(ii) You notify the Administrator that a qualified operator is accessible and that you are resuming operation.

Emission Limitations and Operating Limits

§ 60.2105 What emission limitations must I meet and by when?

(a) You must meet the emission limitations for each CISWI unit, including bypass stack or vent, specified in table 1 of this subpart or tables 5 through 8 of this subpart by the applicable date in § 60.2140. You must be in compliance with the emission limitations of this subpart that apply to you at all times.

(b) An incinerator or air curtain incinerator that commenced construction after November 30, 1999, but no later than June 4, 2010, or that commenced reconstruction or modification on or after June 1, 2001 but no later than August 7, 2013, must continue to meet the emission limits in table 1 of this subpart for units in the incinerator subcategory and § 60.2250 for air curtain incinerators until the units become subject to the requirements of an approved state plan or federal plan that implements subpart DDDD of this part (Emission Guidelines and Compliance Times for Commercial and Industrial Solid Waste Incineration Units).

§ 60.2110 What operating limits must I meet and by when?

(a) If you use a wet scrubber(s) to comply with the emission limitations, you must establish operating limits for up to four operating parameters (as specified in table 2 of this subpart) as described in paragraphs (a)(1) through (4) of this section during the initial performance test:

(1) Maximum charge rate, calculated using one of the two different procedures in paragraph (a)(1)(i) or (ii) of this section, as appropriate:

(i) For continuous and intermittent units, maximum charge rate is 110 percent of the average charge rate measured during the most recent performance test demonstrating compliance with all applicable emission limitations; and

(ii) For batch units, maximum charge rate is 110 percent of the daily charge rate measured during the most recent performance test demonstrating compliance with all applicable emission limitations.

(2) Minimum pressure drop across the wet particulate matter scrubber, which is calculated as the lowest 1-hour average pressure drop across the wet scrubber measured during the most recent performance test demonstrating compliance with the particulate matter emission limitations; or minimum amperage to the wet scrubber, which is calculated as the lowest 1-hour average amperage to the wet scrubber measured during the most recent performance test demonstrating compliance with the particulate matter emission limitations;

(3) Minimum scrubber liquid flow rate, which is calculated as the lowest 1-hour average liquid flow rate at the inlet to the wet acid gas or particulate matter scrubber measured during the most recent performance test demonstrating compliance with all applicable emission limitations; and

(4) Minimum scrubber liquor pH, which is calculated as the lowest 1-hour average liquor pH at the inlet to the wet acid gas scrubber measured during the most recent performance test demonstrating compliance with the HCl emission limitation.

(b) You must meet the operating limits established during the initial performance test 60 days after your CISWI unit reaches the charge rate at which it will operate, but no later than 180 days after its initial startup.

(c) If you use a fabric filter to comply with the emission limitations and you do not use a PM CPMS for monitoring PM compliance, you must operate each fabric filter system such that the bag leak detection system alarm does not sound more than 5 percent of the operating time during a 6-month period. In calculating this operating time percentage, if inspection of the fabric filter demonstrates that no corrective action is required, no alarm time is counted. If corrective action is required, each alarm shall be counted as a minimum of 1 hour. If you take longer than 1 hour to initiate corrective action, the alarm time shall be counted as the actual amount of time taken by you to initiate corrective action.

(d) If you use an electrostatic precipitator to comply with the emission limitations and you do not use a PM CPMS for monitoring PM compliance, you must measure the (secondary) voltage and amperage of the electrostatic precipitator collection plates during the particulate matter performance test. Calculate the average electric power value (secondary voltage × secondary current = secondary electric power) for each test run. The operating limit for the electrostatic precipitator is calculated as the lowest 1-hour average secondary electric power measured during the most recent performance test demonstrating compliance with the particulate matter emission limitations.

(e) If you use activated carbon sorbent injection to comply with the emission limitations, you must measure the sorbent flow rate during the performance testing. The operating limit for the carbon sorbent injection is calculated as the lowest 1-hour average sorbent flow rate measured during the most recent performance test demonstrating compliance with the mercury emission limitations. For energy recovery units, when your unit operates at lower loads, multiply your sorbent injection rate by the load fraction, as defined in this subpart, to determine the required injection rate (*e.g.,* for 50 percent load, multiply the injection rate operating limit by 0.5).

(f) If you use selective noncatalytic reduction to comply with the emission limitations, you must measure the charge rate, the secondary chamber temperature (if applicable to your CISWI unit), and the reagent flow rate during the nitrogen oxides performance testing. The operating limits for the selective noncatalytic reduction are calculated as the highest 1-hour average charge rate, lower secondary chamber temperature, and lowest reagent flow rate measured during the most recent performance test demonstrating compliance with the nitrogen oxides emission limitations.

(g) If you use a dry scrubber to comply with the emission limitations, you must measure the injection rate of each sorbent during the performance testing. The operating limit for the injection rate of each sorbent is calculated as the lowest 1-hour average injection rate or each sorbent measured during the most recent performance test demonstrating compliance with the hydrogen chloride emission limitations. For energy recovery units, when your unit operates at lower loads, multiply your sorbent injection rate by the load fraction, as defined in this subpart, to determine the required injection rate (*e.g.,* for 50 percent load, multiply the injection rate operating limit by 0.5).

(h) If you do not use a wet scrubber, electrostatic precipitator, or fabric filter to comply with the emission limitations, and if you do not determine compliance with your particulate matter emission limitation with either a particulate matter CEMS or a particulate matter CPMS, you must maintain opacity to less than or equal to 10 percent opacity (1-hour block average).

(i) If you use a PM CPMS to demonstrate compliance, you must establish your PM CPMS operating limit and determine compliance with it according to paragraphs (i)(1) through (5) of this section:

(1) Determine your operating limit as the average PM CPMS output value recorded during the performance test or at a PM CPMS output value corresponding to 75 percent of the emission limit if your PM performance test demonstrates compliance below 75 percent of the emission limit. You must verify an existing or establish a new operating limit after each repeated performance test. You must repeat the performance test annually and reassess and adjust the site-specific operating limit in accordance with the results of the performance test:

(i) Your PM CPMS must provide a 4–20 milliamp output, or digital equivalent, and the establishment of its relationship to manual reference method measurements must be determined in units of milliamps;

(ii) Your PM CPMS operating range must be capable of reading PM concentrations from zero to a level equivalent to at least two times your allowable emission limit. If your PM CPMS is an auto-ranging instrument capable of multiple scales, the primary range of the instrument must be capable of reading PM concentration from zero to a level equivalent to two times your allowable emission limit; and

(iii) During the initial performance test or any such subsequent performance test that demonstrates compliance with the PM limit, record and average all milliamp output values, or their digital equivalent, from the PM CPMS for the periods corresponding to the compliance test runs (*e.g.,* average all your PM CPMS output values for three corresponding 2-hour Method 5I test runs).

(2) If the average of your three PM performance test runs are below 75 percent of your PM emission limit, you must calculate an operating limit by establishing a relationship of PM CPMS signal to PM concentration using the PM CPMS instrument zero, the average PM CPMS output values corresponding to the three compliance test runs, and the average PM concentration from the Method 5 or performance test with the procedures in (i)(1) through (5) of this section:

(i) Determine your instrument zero output with one of the following procedures:

(A) Zero point data for *in-situ* instruments should be obtained by removing the instrument from the stack and monitoring ambient air on a test bench;

(B) Zero point data for extractive instruments should be obtained by removing the extractive probe from the stack and drawing in clean ambient air;

(C) The zero point can also can be established obtained by performing manual reference method measurements when the flue gas is free of PM emissions or contains very low PM concentrations (*e.g.,* when your process is not operating, but the fans are operating or your source is combusting only natural gas) and plotting these with the compliance data to find the zero intercept; and

(D) If none of the steps in paragraphs (i)(2)(i)(A) through (C) of this section are possible, you must use a zero output value provided by the manufacturer.

(ii) Determine your PM CPMS instrument average in milliamps, or the digital equivalent, and the average of your corresponding three PM compliance test runs, using equation 1:

$$\bar{x} = \frac{1}{n}\sum_{i=1}^{n} X_1, \bar{y} = \frac{1}{n}\sum_{i=1}^{n} Y_1 \qquad \text{(Eq. 1)}$$

Where:

X_1 = the PM CPMS output data points for the three runs constituting the performance test,

Y_1 = the PM concentration value for the three runs constituting the performance test, and

n = the number of data points.

(iii) With your instrument zero expressed in milliamps, or the digital equivalent, your three run average PM CPMS milliamp value, or its digital equivalent, and your three run average PM concentration from your three compliance tests, determine a relationship of mg/dscm per milliamp or digital signal equivalent with equation 2:

$$R = \frac{Y_1}{(X_1 - z)} \qquad \text{(Eq. 2)}$$

Where:

R = the relative mg/dscm per milliamp or digital equivalent for your PM CPMS,

Y_1 = the three run average mg/dscm PM concentration,

X_1 = the three run average milliamp or digital signal output from you PM CPMS, and

z = the milliamp or digital signal equivalent of your instrument zero determined from paragraph (2)(i) of this section.

(iv) Determine your source specific 30-day rolling average operating limit using the mg/dscm per milliamp or digital value from equation 2 in equation 3, below. This sets your operating limit at the PM CPMS output value corresponding to 75 percent of your emission limit:

$$O_l = z + \frac{0.75(L)}{R} \qquad \text{(Eq. 3)}$$

Where:

O_l = the operating limit for your PM CPMS on a 30-day rolling average, in milliamps or their digital signal equivalent,

L = your source emission limit expressed in mg/dscm,

z = your instrument zero in milliamps or the digital equivalent, determined from paragraph (2)(i) of this secction, and

R = the relative mg/dscm per milliamp or digital signal output equivalent for your PM CPMS, from equation 2.

(3) If the average of your three PM compliance test runs is at or above 75 percent of your PM emission limit you must determine your operating limit by averaging the PM CPMS milliamp or digital signal output corresponding to your three PM performance test runs that demonstrate compliance with the emission limit using equation 4 and you must submit all compliance test and PM CPMS data according to the reporting requirements in paragraph (i)(5) of this section:

$$O_h = \frac{1}{n}\sum_{i=1}^{n} X_1 \qquad \text{(Eq. 4)}$$

Where:

X_1 = the PM CPMS data points for all runs i,

n = the number of data points, and

O_h = your site specific operating limit, in milliamps or digital signal equivalent.

(4) To determine continuous compliance, you must record the PM CPMS output data for all periods when the process is operating and the PM CPMS is not out-of-control. You must demonstrate continuous compliance by using all quality-assured hourly average data collected by the PM CPMS for all operating hours to calculate the arithmetic average operating parameter in units of the operating limit (*e.g.,* milliamps or digital signal bits, PM concentration, raw data signal) on a 30-day rolling average basis.

(5) For PM performance test reports used to set a PM CPMS operating limit, the electronic submission of the test report must also include the make and model of the PM CPMS instrument, serial number of the instrument, analytical principle of the instrument (*e.g.,* beta attenuation), span of the instruments primary analytical range, milliamp or digital signal value equivalent to the instrument zero output, technique by which this zero value was determined, and the average milliamp or digital signals corresponding to each PM compliance test run.

§ 60.2115 What if I do not use a wet scrubber, fabric filter, activated carbon injection, selective noncatalytic reduction, an electrostatic precipitator, or a dry scrubber to comply with the emission limitations?

If you use an air pollution control device other than a wet scrubber, activated carbon injection, selective noncatalytic reduction, fabric filter, an electrostatic precipitator, or a dry scrubber or limit emissions in some other manner, including material balances, to comply with the emission limitations under § 60.2105, you must petition the EPA Administrator for specific operating limits to be established during the initial performance test and continuously monitored thereafter. You must submit the petition at least sixty days before the performance test is scheduled to begin. Your petition must include the five items listed in paragraphs (a) through (e) of this section:

(a) Identification of the specific parameters you propose to use as additional operating limits;

(b) A discussion of the relationship between these parameters and emissions of regulated pollutants, identifying how emissions of regulated pollutants change with changes in these parameters and how limits on these parameters will serve to limit emissions of regulated pollutants;

(c) A discussion of how you will establish the upper and/or lower values for these parameters which will establish the operating limits on these parameters;

(d) A discussion identifying the methods you will use to measure and the instruments you will use to monitor these parameters, as well as the relative accuracy and precision of these methods and instruments; and

(e) A discussion identifying the frequency and methods for recalibrating the instruments you will use for monitoring these parameters.

Performance Testing

§ 60.2125 How do I conduct the initial and annual performance test?

(a) All performance tests must consist of a minimum of three test runs conducted under conditions representative of normal operations.

(b) You must document that the waste burned during the performance test is representative of the waste burned under normal operating conditions by maintaining a log of the quantity of waste burned (as required in § 60.2175(b)(1)) and the types of waste burned during the performance test.

(c) All performance tests must be conducted using the minimum run duration specified in table 1 of this subpart or tables 5 through 8 of this subpart.

(d) Method 1 of appendix A of this part must be used to select the sampling location and number of traverse points.

(e) Method 3A or 3B of appendix A of this part must be used for gas composition analysis, including measurement of oxygen concentration. Method 3A or 3B of appendix A of this part must be used simultaneously with each method.

(f) All pollutant concentrations, except for opacity, must be adjusted to 7 percent oxygen using equation 5 of this section:

$$C_{adj} = C_{meas}\ (20.9-7)/(20.9-\%O_2) \qquad \text{(Eq. 5)}$$

Where:

C_{adj} = pollutant concentration adjusted to 7 percent oxygen;
C_{meas} = pollutant concentration measured on a dry basis;
(20.9–7) = 20.9 percent oxygen–7 percent oxygen (defined oxygen correction basis);
20.9 = oxygen concentration in air, percent; and
$\%O_2$ = oxygen concentration measured on a dry basis, percent.

(g) You must determine dioxins/furans toxic equivalency by following the procedures in paragraphs (g)(1) through (4) of this section:

(1) Measure the concentration of each dioxin/furan tetra-through octa-chlorinated isomer emitted using EPA Method 23 at 40 CFR part 60, appendix A–7;

(2) Quantify isomers meeting identification criteria 2, 3, 4, and 5 in Section 5.3.2.5 of Method 23, regardless of whether the isomers meet identification criteria 1 and 7. You must quantify the isomers per Section 9.0 of Method 23. (Note: You may reanalyze the sample aliquot or split to reduce the number of isomers not meeting identification criteria 1 or 7 of Section 5.3.2.5.);

(3) For each dioxin/furan (tetra-through octa-chlorinated) isomer measured in accordance with paragraphs (g)(1) and (2) of this section, multiply the isomer concentration by its corresponding toxic equivalency factor specified in table 3 of this subpart; and

(4) Sum the products calculated in accordance with paragraph (g)(3) of this section to obtain the total concentration of dioxins/furans emitted in terms of toxic equivalency.

(h) Method 22 at 40 CFR part 60, appendix A–7 of this part must be used to determine compliance with the fugitive ash emission limit in table 1 of this subpart or tables 5 through 8 of this subpart.

(i) If you have an applicable opacity operating limit, you must determine compliance with the opacity limit using Method 9 at 40 CFR part 60, appendix A–4, based on three 1-hour blocks consisting of ten 6-minute average opacity values, unless you are required to install a continuous opacity monitoring system, consistent with §§ 60.2145 and 60.2165.

(j) You must determine dioxins/furans total mass basis by following the procedures in paragraphs (j)(1) through (3) of this section:

(1) Measure the concentration of each dioxin/furan tetra-through octa-chlorinated isomer emitted using EPA Method 23 at 40 CFR part 60, appendix A–7;

(2) Quantify isomers meeting identification criteria 2, 3, 4, and 5 in Section 5.3.2.5 of Method 23, regardless of whether the isomers meet identification criteria 1 and 7. You must quantify the isomers per Section 9.0 of Method 23. (Note: You may reanalyze the sample aliquot or split to reduce the number of isomers not meeting identification criteria 1 or 7 of Section 5.3.2.5.); and

(3) Sum the quantities measured in accordance with paragraphs (j)(1) and (2) of this section to obtain the total concentration of dioxins/furans emitted in terms of total mass basis.

§ 60.2130 How are the performance test data used?

You use results of performance tests to demonstrate compliance with the emission limitations in table 1 of this subpart or tables 5 through 8 of this subpart.

Initial Compliance Requirements

§ 60.2135 How do I demonstrate initial compliance with the emission limitations and establish the operating limits?

You must conduct a performance test, as required under §§ 60.2125 and 60.2105 to determine compliance with the emission limitations in table 1 of this subpart or tables 5 through 8 of this subpart, to establish compliance with any opacity operating limit in § 60.2110, to establish the kiln-specific emission limit in § 60.2145(y), as applicable, and to establish operating limits using the procedures in §§ 60.2110 or 60.2115. The performance test must be conducted using the test methods listed in table 1 of this subpart or tables 5 through 8 of this subpart and the procedures in § 60.2125. The use of the bypass stack during a performance test shall invalidate the performance test. You must conduct a performance evaluation of each continuous monitoring system within 60 days of installation of the monitoring system.

§ 60.2140 By what date must I conduct the initial performance test?

(a) The initial performance test must be conducted within 60 days after your CISWI unit reaches the charge rate at which it will operate, but no later than 180 days after its initial startup.

(b) If you commence or recommence combusting a solid waste at an existing combustion unit at any commercial or industrial facility, and you conducted a test consistent with the provisions of this subpart while combusting the solid waste within the 6 months preceding the reintroduction of that solid waste in the combustion chamber, you do not need to retest until 6 months from the date you reintroduce that solid waste.

(c) If you commence or recommence combusting a solid waste at an existing combustion unit at any commercial or industrial facility and you have not conducted a performance test consistent with the provisions of this subpart while combusting the solid waste within the 6 months preceding the reintroduction of that solid waste in the combustion chamber, you must conduct a performance test within 60 days from the date you reintroduce that solid waste.

§ 60.2141 By what date must I conduct the initial air pollution control device inspection?

(a) The initial air pollution control device inspection must be conducted within 60 days after installation of the control device and the associated CISWI unit reaches the charge rate at which it will operate, but no later than 180 days after the device's initial startup.

(b) Within 10 operating days following an air pollution control device inspection, all necessary repairs must be completed unless the owner or operator obtains written approval from the state agency establishing a date whereby all necessary repairs of the designated facility must be completed.

Continuous Compliance Requirements

§ 60.2145 How do I demonstrate continuous compliance with the emission limitations and the operating limits?

(a) *Compliance with standards.* (1) The emission standards and operating requirements set forth in this subpart apply at all times;

(2) If you cease combusting solid waste, you may opt to remain subject to the provisions of this subpart. Consistent with the definition of CISWI unit, you are subject to the requirements of this subpart at least 6 months following the last date of solid waste combustion. Solid waste combustion is ceased when solid waste is not in the combustion chamber (*i.e.*, the solid waste feed to the combustor has been cut off for a period of time not less than the solid waste residence time);

(3) If you cease combusting solid waste, you must be in compliance with any newly applicable standards on the effective date of the waste-to-fuel switch. The effective date of the waste-to-fuel switch is a date selected by you, that must be at least 6 months from the date that you ceased combusting solid waste, consistent with § 60.2145(a)(2). Your source must remain in compliance with this subpart until the effective date of the waste-to-fuel switch;

(4) If you own or operate an existing commercial or industrial combustion unit that combusted a fuel or non-waste material, and you commence or recommence combustion of solid waste, you are subject to the provisions of this subpart as of the first day you introduce or reintroduce solid waste to the combustion chamber, and this date constitutes the effective date of the fuel-to-waste switch. You must complete all initial compliance demonstrations for any section 112 standards that are applicable to your facility before you commence or recommence combustion of solid waste. You must provide 30 days prior notice of the effective date of the waste-to-fuel switch. The notification must identify:

(i) The name of the owner or operator of the CISWI unit, the location of the source, the emissions unit(s) that will cease burning solid waste, and the date of the notice;

(ii) The currently applicable subcategory under this subpart, and any 40 CFR part 63 subpart and subcategory that will be applicable after you cease combusting solid waste;

(iii) The fuel(s), non-waste material(s) and solid waste(s) the CISWI unit is currently combusting and has combusted over the past 6 months, and the fuel(s) or non-waste materials the unit will commence combusting;

(iv) The date on which you became subject to the currently applicable emission limits; and

(v) The date upon which you will cease combusting solid waste, and the date (if different) that you intend for any new requirements to become applicable (*i.e.*, the effective date of the waste-to-fuel switch), consistent with paragraphs (a)(2) and (3) of this section.

(5) All air pollution control equipment necessary for compliance with any newly applicable emissions limits which apply as a result of the cessation or commencement or recommencement of combusting solid waste must be installed and operational as of the effective date of the waste-to-fuel, or fuel-to-waste switch.

(6) All monitoring systems necessary for compliance with any newly applicable monitoring requirements which apply as a result of the cessation or commencement or recommencement of combusting solid waste must be installed and operational as of the effective date of the waste-to-fuel, or fuel-to-waste switch. All calibration and drift checks must be performed as of the effective date of the waste-to-fuel, or fuel-to-waste switch. Relative accuracy tests must be performed as of the performance test deadline for PM CEMS (if PM CEMS are elected to demonstrate continuous compliance with the particulate matter emission limits). Relative accuracy testing for other CEMS need not be repeated if that testing was previously performed consistent with Clean Air Act section 112 monitoring requirements or monitoring requirements under this subpart.

(b) You must conduct an annual performance test for the pollutants listed in table 1 of this subpart or tables 5 through 8 of this subpart and opacity for each CISWI unit as required under § 60.2125. The annual performance test must be conducted using the test methods listed in table 1 of this subpart or tables 5 through 8 of this subpart and the procedures in § 60.2125. Annual performance tests are not required if you use CEMS or continuous opacity monitoring systems to determine compliance.

(c) You must continuously monitor the operating parameters specified in § 60.2110 or established under § 60.2115 and as specified in § 60.2170. Use 3-hour block average values to determine compliance (except for baghouse leak detection system alarms) unless a different averaging period is established under § 60.2115 or, for energy recovery units, where the averaging time for each operating parameter is a 30-day rolling, calculated each hour as the average of the previous 720 operating hours. Operation above the established maximum, below the established minimum, or outside the allowable range of operating limits specified in paragraph (a) of this section constitutes a deviation from your operating limits established under this subpart, except during performance tests conducted to determine compliance with the emission and operating limits or to establish new operating limits. Operating limits are confirmed or reestablished during performance tests.

(d) You must burn only the same types of waste and fuels used to establish subcategory applicability (for energy recovery units) and operating limits during the performance test.

(e) For energy recovery units, incinerators, and small remote units, you must perform an annual visual emissions test for ash handling.

(f) For energy recovery units, you must conduct an annual performance test for opacity (except where particulate matter CEMS or continuous opacity monitoring systems are used are used) and the pollutants listed in table 6 of this subpart.

(g) You may elect to demonstrate continuous compliance with the carbon monoxide emission limit using a carbon monoxide CEMS according to the following requirements:

(1) You must measure emissions according to § 60.13 to calculate 1-hour arithmetic averages, corrected to 7 percent oxygen. CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content. You must demonstrate initial compliance with the carbon monoxide emissions limit using a 30-day rolling average of these 1-hour arithmetic average emission concentrations, including CEMS data during startup and shutdown as defined in this subpart, calculated using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, appendix A–7 of this part; and

(2) Operate the carbon monoxide CEMS in accordance with the requirements of performance specification 4A of appendix B of this part and quality assurance procedure 1 of appendix F of this part.

(h) Coal and liquid/gas energy recovery units with average annual heat input rates greater than or equal to 250 MMBtu/hr may elect to demonstrate continuous compliance with the particulate matter emissions limit using a particulate matter CEMS according to the procedures in § 60.2165(n) instead of the particulate matter continuous parameter monitoring system (CPMS) specified in § 60.2145. Coal and liquid/gas energy recovery units with annual average heat input rates less than 250 MMBtu/hr, incinerators, and small remote incinerators may also elect to demonstrate compliance using a particulate matter CEMS according to the procedures in § 60.2165(n) instead of particulate matter testing with EPA Method 5 at 40 CFR part 60, appendix A–3 and, if applicable, the continuous opacity monitoring requirements in paragraph (i) of this section.

(i) For energy recovery units with annual average heat input rates greater than or equal to 10 MMBtu/hour and less than 250 MMBtu/hr, you must install, operate, certify and maintain a continuous opacity monitoring system (COMS) according to the procedures in § 60.2165.

(j) For waste-burning kilns, you must conduct an annual performance test for cadmium, lead, dioxins/furans and hydrogen chloride as listed in table 7 of this subpart. If you do not use an acid gas wet scrubber or dry scrubber, you must determine compliance with the hydrogen chloride emissions limit according to the requirements in paragraph (j)(1) of this section. You must determine compliance with the mercury emissions limit using a mercury CEMS according to paragraph (j)(2) of this section. You must determine compliance with nitrogen oxides, sulfur dioxide, and carbon monoxide using CEMS. You must determine compliance with particulate matter using CPMS:

(1) If you monitor compliance with the HCl emissions limit by operating an HCl CEMS, you must do so in accordance with Performance Specification 15 (PS 15) of appendix B to 40 CFR part 60, or, PS 18 of appendix B to 40 CFR part 60. You must operate, maintain, and quality assure a HCl CEMS installed and certified under PS 15 according to the quality assurance requirements in Procedure 1 of appendix F to 40 CFR part 60 except that the Relative Accuracy Test Audit requirements of Procedure 1 must be replaced with the validation requirements and criteria of sections 11.1.1 and 12.0 of PS 15. You must operate, maintain and quality assure a HCl CEMS installed and certified under PS 18 according to the quality assurance requirements in Procedure 6 of appendix F to 40 CFR part 60. For any performance specification that you use, you must use Method 321 of appendix A to 40 CFR part 63 as the reference test method for conducting relative accuracy testing. The span value and calibration requirements in paragraphs (j)(1)(i) and (ii) of this section apply to all HCl CEMS used under this subpart:

(i) You must use a measurement span value for any HCl CEMS of 0–10 ppmvw unless the monitor is installed on a kiln without an inline raw mill. Kilns without an inline raw mill may use a higher span value sufficient to quantify all expected emissions concentrations. The HCl CEMS data recorder output range must include the full range of expected HCl concentration values which would include those expected during "mill off" conditions. The corresponding data recorder range shall be documented in the site-specific monitoring plan and associated records;

(ii) In order to quality assure data measured above the span value, you must use one of the three options in paragraphs (j)(1)(ii)(A) through (C) of this section:

(A) Include a second span that encompasses the HCl emission concentrations expected to be encountered during "mill off" conditions. This second span may be rounded to a multiple of 5 ppm of total HCl. The requirements of the appropriate HCl monitor performance specification shall be followed for this second span with the exception that a RATA with the mill off is not required;

(B) Quality assure any data above the span value by proving instrument linearity beyond the span value established in paragraph (j)(1)(i) of this section using the following procedure. Conduct a weekly "above span linearity" calibration challenge of the monitoring system using a reference gas with a certified value greater than your highest expected hourly concentration or greater than 75% of the highest measured hourly concentration. The "above span" reference gas must meet the requirements of the applicable performance specification and must be introduced to the measurement system at the probe. Record and report the results of this procedure as you would for a daily calibration. The "above span linearity" challenge is successful if the value measured by the HCl CEMS falls within 10 percent of the certified value of the reference gas. If the value measured by the HCl CEMS during the above span linearity challenge exceeds 10 percent of the certified value of the reference gas, the monitoring system must be evaluated and repaired and a new "above span linearity" challenge met before returning the HCl CEMS to service, or data above span from the HCl CEMS must be subject to the quality assurance procedures established in (j)(1)(ii)(D) of this section. In this manner values measured by the HCl CEMS during the above span linearity challenge exceeding +/− 20 percent of the certified value of the reference gas must be normalized using equation 6;

(C) Quality assure any data above the span value established in paragraph (j)(1)(i) of this section using the following procedure. Any time two consecutive one-hour average measured concentration of HCl exceeds the span value you must, within 24 hours before or after, introduce a higher, "above span" HCl reference gas standard to the HCl CEMS. The "above span" reference gas must meet the requirements of the applicable performance specification and target a concentration level between 50 and 150 percent of the highest expected hourly concentration measured during the period of measurements above span, and must be introduced at the probe. While this target represents a desired concentration range that is not always achievable in practice, it is expected that the intent to meet this range is demonstrated by the value of the reference gas. Expected values may include above span calibrations done before or after the above-span measurement period. Record and report the results of this procedure as you would for a daily calibration. The "above span" calibration is successful if the value measured by the HCl CEMS is within 20 percent of the certified value of the reference gas. If the value measured by the HCl CEMS is not within 20 percent of the certified value of the reference gas, then you must normalize the stack gas values measured above span as described in paragraph (j)(1)(ii)(D) of this section. If the "above span" calibration is conducted during the period when measured emissions are above span and there is a failure to collect the one data point in an hour due to the calibration duration, then you must determine the emissions average for that missed hour as the average of hourly averages for the hour preceding the missed hour and the hour following the missed hour. In an hour where an "above span" calibration is being conducted and one or more data points are collected, the emissions average is represented by the average of all valid data points collected in that hour;

(D) In the event that the "above span" calibration is not successful (*i.e.,* the HCl CEMS measured value is not within 20 percent of the certified value of the reference gas), then you must normalize the one-hour average stack gas values measured above the span during the 24-hour period preceding or following the "above span" calibration for reporting based on the HCl CEMS response to the reference gas as shown in equation 6:

$$\frac{Certified\ reference\ gas\ value}{Measured\ value\ of\ reference\ gas} x\ Measured\ stack\ gas\ result = Normalized\ stack\ gas\ result \qquad (Eq. 6)$$

Only one "above span" calibration is needed per 24-hour period.

(2) Compliance with the mercury emissions limit must be determined using a mercury CEMS according to the following requirements:

(i) You must operate a CEMS system in accordance with performance specification 12A of 40 CFR part 60, appendix B or a sorbent trap based integrated monitor in accordance with performance specification 12B of 40 CFR part 60, appendix B. The duration of the performance test must be a calendar month. For each calendar month in which the waste-burning kiln operates, hourly mercury concentration data, and stack gas volumetric flow rate data must be obtained. You must demonstrate compliance with the mercury emissions limit using a 30-day rolling average of these 1-hour mercury concentrations, including CEMS data during startup and shutdown as defined in this subpart, calculated using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, appendix A–7 of this part. CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content;

(ii) Owners or operators using a mercury CEMS must install, operate, calibrate, and maintain an instrument for continuously measuring and recording the mercury mass emissions rate to the atmosphere according to the requirements of performance specifications 6 and 12A of 40 CFR part 60, appendix B, and quality assurance procedure 6 of 40 CFR part 60, appendix F; and

(iii) The owner or operator of a waste-burning kiln must demonstrate initial compliance by operating a mercury CEMS while the raw mill of the in-line kiln/raw mill is operating under normal conditions and including at least one period when the raw mill is off.

(k) If you use an air pollution control device to meet the emission limitations in this subpart, you must conduct an initial and annual inspection of the air pollution control device. The inspection must include, at a minimum, the following:

(1) Inspect air pollution control device(s) for proper operation; and.

(2) Develop a site-specific monitoring plan according to the requirements in paragraph (l) of this section. This requirement also applies to you if you petition the EPA Administrator for alternative monitoring parameters under § 60.13(i).

(l) For each continuous monitoring system required in this section, you must develop and submit to the EPA Administrator for approval a site-specific monitoring plan according to the requirements of this paragraph (l) that addresses paragraphs (l)(1)(i) through (vi) of this section:

(1) You must submit this site-specific monitoring plan at least 60 days before your initial performance evaluation of your continuous monitoring system:

(i) Installation of the continuous monitoring system sampling probe or other interface at a measurement location relative to each affected process unit such that the measurement is representative of control of the exhaust emissions (*e.g.*, on or downstream of the last control device);

(ii) Performance and equipment specifications for the sample interface, the pollutant concentration or parametric signal analyzer and the data collection and reduction systems.

(iii) Performance evaluation procedures and acceptance criteria (*e.g.*, calibrations);

(iv) Ongoing operation and maintenance procedures in accordance with the general requirements of § 60.11(d);

(v) Ongoing data quality assurance procedures in accordance with the general requirements of § 60.13; and

(vi) Ongoing recordkeeping and reporting procedures in accordance with the general requirements of § 60.7(b), (c), (c)(1), (c)(4), (d), (e), (f), and (g).

(2) You must conduct a performance evaluation of each continuous monitoring system in accordance with your site-specific monitoring plan.

(3) You must operate and maintain the continuous monitoring system in continuous operation according to the site-specific monitoring plan.

(m) If you have an operating limit that requires the use of a flow monitoring system, you must meet the requirements in paragraphs (l) and (m)(1) through (4) of this section:

(1) Install the flow sensor and other necessary equipment in a position that provides a representative flow;

(2) Use a flow sensor with a measurement sensitivity at full scale of no greater than 2 percent;

(3) Minimize the effects of swirling flow or abnormal velocity distributions due to upstream and downstream disturbances; and

(4) Conduct a flow monitoring system performance evaluation in accordance with your monitoring plan at the time of each performance test but no less frequently than annually.

(n) If you have an operating limit that requires the use of a pressure monitoring system, you must meet the requirements in paragraphs (l) and (n)(1) through (6) of this section:

(1) Install the pressure sensor(s) in a position that provides a representative measurement of the pressure (*e.g.*, PM scrubber pressure drop);

(2) Minimize or eliminate pulsating pressure, vibration, and internal and external corrosion;

(3) Use a pressure sensor with a minimum tolerance of 1.27 centimeters of water or a minimum tolerance of 1 percent of the pressure monitoring system operating range, whichever is less;

(4) Perform checks at the frequency outlined in your site-specific monitoring plan to ensure pressure measurements are not obstructed (*e.g.*, check for pressure tap plugging daily);

(5) Conduct a performance evaluation of the pressure monitoring system in accordance with your monitoring plan at the time of each performance test but no less frequently than annually; and

(6) If at any time the measured pressure exceeds the manufacturer's specified maximum operating pressure range, conduct a performance evaluation of the pressure monitoring system in accordance with your monitoring plan and confirm that the pressure monitoring system continues to meet the performance requirements in your monitoring plan. Alternatively, install and verify the operation of a new pressure sensor.

(o) If you have an operating limit that requires a pH monitoring system, you must meet the requirements in paragraphs (l) and (o)(1) through (4) of this section:

(1) Install the pH sensor in a position that provides a representative measurement of scrubber effluent pH;

(2) Ensure the sample is properly mixed and representative of the fluid to be measured;

(3) Conduct a performance evaluation of the pH monitoring system in

accordance with your monitoring plan at least once each process operating day; and

(4) Conduct a performance evaluation (including a two-point calibration with one of the two buffer solutions having a pH within 1 of the pH of the operating limit) of the pH monitoring system in accordance with your monitoring plan at the time of each performance test but no less frequently than quarterly.

(p) If you have an operating limit that requires a secondary electric power monitoring system for an electrostatic precipitator, you must meet the requirements in paragraphs (l) and (p)(1) and (2) of this section:

(1) Install sensors to measure (secondary) voltage and current to the precipitator collection plates; and

(2) Conduct a performance evaluation of the electric power monitoring system in accordance with your monitoring plan at the time of each performance test but no less frequently than annually.

(q) If you have an operating limit that requires the use of a monitoring system to measure sorbent injection rate (*e.g.*, weigh belt, weigh hopper, or hopper flow measurement device), you must meet the requirements in paragraphs (l) and (q)(1) and (2) of this section:

(1) Install the system in a position(s) that provides a representative measurement of the total sorbent injection rate; and

(2) Conduct a performance evaluation of the sorbent injection rate monitoring system in accordance with your monitoring plan at the time of each performance test but no less frequently than annually.

(r) If you elect to use a fabric filter bag leak detection system to comply with the requirements of this subpart, you must install, calibrate, maintain, and continuously operate a bag leak detection system as specified in paragraphs (l) and (r)(1) through (5) of this section:

(1) Install a bag leak detection sensor(s) in a position(s) that will be representative of the relative or absolute particulate matter loadings for each exhaust stack, roof vent, or compartment (*e.g.*, for a positive pressure fabric filter) of the fabric filter;

(2) Use a bag leak detection system certified by the manufacturer to be capable of detecting particulate matter emissions at concentrations of 10 milligrams per actual cubic meter or less;

(3) Conduct a performance evaluation of the bag leak detection system in accordance with your monitoring plan and consistent with the guidance provided in EPA–454/R–98–015 (incorporated by reference, *see* § 60.17);

(4) Use a bag leak detection system equipped with a device to continuously record the output signal from the sensor; and

(5) Use a bag leak detection system equipped with a system that will sound an alarm when an increase in relative particulate matter emissions over a preset level is detected. The alarm must be located where it is observed readily by plant operating personnel.

(s) For facilities using a CEMS to demonstrate compliance with the sulfur dioxide emission limit, compliance with the sulfur dioxide emission limit may be demonstrated by using the CEMS specified in § 60.2165 to measure sulfur dioxide. CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content. You must calculate a 30-day rolling average of the 1-hour arithmetic average emission concentrations, including CEMS data during startup and shutdown as defined in this subpart, calculated using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, Appendix A–7 of this part. The sulfur dioxide CEMS must be operated according to performance specification 2 in appendix B of this part and must follow the procedures and methods specified in paragraph (s) of this section. For sources that have actual inlet emissions less than 100 parts per million dry volume, the relative accuracy criterion for inlet sulfur dioxide CEMS should be no greater than 20 percent of the mean value of the reference method test data in terms of the units of the emission standard, or 5 parts per million dry volume absolute value of the mean difference between the reference method and the CEMS, whichever is greater:

(1) During each relative accuracy test run of the CEMS required by performance specification 2 in appendix B of this part, collect sulfur dioxide and oxygen (or carbon dioxide) data concurrently (or within a 30- to 60-minute period) with both the CEMS and the test methods specified in paragraphs (s)(1)(i) and (ii) of this section:

(i) For sulfur dioxide, EPA Reference Method 6 or 6C, or as an alternative ANSI/ASME PTC 19.10–1981 (incorporated by reference, *see* § 60.17) must be used; and

(ii) For oxygen (or carbon dioxide), EPA Reference Method 3A or 3B, or as an alternative ANSI/ASME PTC 19.10–1981 (incorporated by reference, *see* § 60.17), must be used.

(2) The span value of the CEMS at the inlet to the sulfur dioxide control device must be 125 percent of the maximum estimated hourly potential sulfur dioxide emissions of the unit subject to this subpart. The span value of the CEMS at the outlet of the sulfur dioxide control device must be 50 percent of the maximum estimated hourly potential sulfur dioxide emissions of the unit subject to this subpart.

(3) Conduct accuracy determinations quarterly and calibration drift tests daily in accordance with procedure 1 in appendix F of this part.

(t) For facilities using a CEMS to demonstrate continuous compliance with the nitrogen oxides emission limit, compliance with the nitrogen oxides emission limit may be demonstrated by using the CEMS specified in § 60.2165 to measure nitrogen oxides. CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content. You must calculate a 30-day rolling average of the 1-hour arithmetic average emission concentrations, including CEMS data during startup and shutdown as defined in this subpart, using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, appendix A–7 of this part. The nitrogen oxides CEMS must be operated according to performance specification 2 in appendix B of this part and must follow the procedures and methods specified in paragraphs (t)(1) through (4) of this section:

(1) During each relative accuracy test run of the CEMS required by performance specification 2 of appendix B of this part, collect nitrogen oxides and oxygen (or carbon dioxide) data concurrently (or within a 30- to 60-minute period) with both the CEMS and the test methods specified in paragraphs (t)(1)(i) and (ii) of this section:

(i) For nitrogen oxides, EPA Reference Method 7 or 7E at 40 CFR part 60, appendix A–4 must be used; and

(ii) For oxygen (or carbon dioxide), EPA Reference Method 3A or 3B at 40 CFR part 60, appendix A–3, or as an alternative ANSI/ASME PTC 19–10.1981 (incorporated by reference, *see* § 60.17), as applicable, must be used.

(2) The span value of the continuous emission monitoring system must be 125 percent of the maximum estimated hourly potential nitrogen oxide emissions of the unit.

(3) Conduct accuracy determinations quarterly and calibration drift tests daily in accordance with procedure 1 in appendix F of this part.

(4) The owner or operator of an affected facility may request that

compliance with the nitrogen oxides emission limit be determined using carbon dioxide measurements corrected to an equivalent of 7 percent oxygen. If carbon dioxide is selected for use in diluent corrections, the relationship between oxygen and carbon dioxide levels must be established during the initial performance test according to the procedures and methods specified in paragraphs (t)(4)(i) through (iv) of this section. This relationship may be re-established during performance compliance tests:

(i) The fuel factor equation in Method 3B must be used to determine the relationship between oxygen and carbon dioxide at a sampling location. Method 3A or 3B, or as an alternative ANSI/ASME PTC 19.10–1981 (incorporated by reference, *see* § 60.17), as applicable, must be used to determine the oxygen concentration at the same location as the carbon dioxide monitor;

(ii) Samples must be taken for at least 30 minutes in each hour;

(iii) Each sample must represent a 1-hour average; and

(iv) A minimum of three runs must be performed.

(u) For facilities using a CEMS to demonstrate continuous compliance with any of the emission limits of this subpart, you must complete the following:

(1) Demonstrate compliance with the appropriate emission limit(s) using a 30-day rolling average of 1-hour arithmetic average emission concentrations, including CEMS data during startup and shutdown as defined in this subpart, calculated using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, appendix A–7 of this part. CEMS data during startup and shutdown, as defined in the subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content; and

(2) Operate all CEMS in accordance with the applicable procedures under appendices B and F of this part.

(v) Use of the bypass stack at any time is an emissions standards deviation for particulate matter, HCl, Pb, Cd, Hg, NO_X, SO_2, and dioxin/furans.

(w) For energy recovery units with a design heat input capacity of 100 MMBtu per hour or greater that do not use a carbon monoxide CEMS, you must install, operate, and maintain a oxygen analyzer system as defined in § 60.2265 according to the procedures in paragraphs (w)(1) through (4) of this section:

(1) The oxygen analyzer system must be installed by the initial performance test date specified in § 60.2140;

(2) You must operate the oxygen trim system within compliance with paragraph (w)(3) of this section at all times;

(3) You must maintain the oxygen level such that the 30-day rolling average that is established as the operating limit for oxygen is not below the lowest hourly average oxygen concentration measured during the most recent CO performance test; and

(4) You must calculate and record a 30-day rolling average oxygen concentration using equation 19–19 in section 12.4.1 of EPA Reference Method 19 of Appendix A–7 of this part.

(x) For energy recovery units with annual average heat input rates greater than or equal to 250 MMBtu/hour and waste-burning kilns, you must install, calibrate, maintain, and operate a PM CPMS and record the output of the system as specified in paragraphs (x)(1) through (8) of this section. For other energy recovery units, you may elect to use PM CPMS operated in accordance with this section. PM CPMS are suitable in lieu of using other CMS for monitoring PM compliance (*e.g.,* bag leak detectors, ESP secondary power, PM scrubber pressure):

(1) Install, calibrate, operate, and maintain your PM CPMS according to the procedures in your approved site-specific monitoring plan developed in accordance with paragraphs (l) and (x)(1)(i) through (iii) of this section:

(i) The operating principle of the PM CPMS must be based on in-stack or extractive light scatter, light scintillation, beta attenuation, or mass accumulation detection of the exhaust gas or representative sample. The reportable measurement output from the PM CPMS must be expressed as milliamps or the digital signal equivalent;

(ii) The PM CPMS must have a cycle time (*i.e.,* period required to complete sampling, measurement, and reporting for each measurement) no longer than 60 minutes; and

(iii) The PM CPMS must be capable of detecting and responding to particulate matter concentrations increments no greater than 0.5 mg/actual cubic meter.

(2) During the initial performance test or any such subsequent performance test that demonstrates compliance with the PM limit, you must adjust the site-specific operating limit in accordance with the results of the performance test according to the procedures specified in § 60.2110.

(3) Collect PM CPMS hourly average output data for all energy recovery unit or waste-burning kiln operating hours. Express the PM CPMS output as milliamps.

(4) Calculate the arithmetic 30-day rolling average of all of the hourly average PM CPMS output collected during all energy recovery unit or waste-burning kiln operating hours data (milliamps or their digital equivalent).

(5) You must collect data using the PM CPMS at all times the energy recovery unit or waste-burning kiln is operating and at the intervals specified in paragraph (x)(1)(ii) of this section, except for periods of monitoring system malfunctions, repairs associated with monitoring system malfunctions, required monitoring system quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments), and any scheduled maintenance as defined in your site-specific monitoring plan.

(6) You must use all the data collected during all energy recovery unit or waste-burning kiln operating hours in assessing the compliance with your operating limit except:

(i) Any data collected during monitoring system malfunctions, repairs associated with monitoring system malfunctions, or required monitoring system quality assurance or quality control activities conducted during monitoring system malfunctions are not used in calculations (report any such periods in your annual deviation report);

(ii) Any data collected during periods when the monitoring system is out of control as specified in your site-specific monitoring plan, repairs associated with periods when the monitoring system is out of control, or required monitoring system quality assurance or quality control activities conducted during out-of-control periods are not used in calculations (report emissions or operating levels and report any such periods in your annual deviation report);

(iii) Any PM CPMS data recorded during periods of CEMS data during startup and shutdown, as defined in this subpart.

(7) You must record and make available upon request results of PM CPMS system performance audits, as well as the dates and duration of periods from when the PM CPMS is out of control until completion of the corrective actions necessary to return the PM CPMS to operation consistent with your site-specific monitoring plan.

(8) For any deviation of the 30-day rolling average PM CPMS average value from the established operating parameter limit, you must:

(i) Within 48 hours of the deviation, visually inspect the air pollution control device;

(ii) If inspection of the air pollution control device identifies the cause of the deviation, take corrective action as soon as possible and return the PM CPMS measurement to within the established value;

(iii) Within 30 days of the deviation or at the time of the annual compliance test, whichever comes first, conduct a PM emissions compliance test to determine compliance with the PM emissions limit and to verify. Within 45 days of the deviation, you must re-establish the CPMS operating limit. You are not required to conduct additional testing for any deviations that occur between the time of the original deviation and the PM emissions compliance test required under paragraph (x) of this section; and

(iv) PM CPMS deviations leading to more than four required performance tests in a 12-month process operating period (rolling monthly) constitute a violation of this subpart.

(y) When there is an alkali bypass and/or an in-line coal mill that exhaust emissions through a separate stack(s), the combined emissions are subject to the emission limits applicable to waste-burning kilns. To determine the kiln-specific emission limit for demonstrating compliance, you must:

(1) Calculate a kiln-specific emission limit using equation 7:

$$C_{ks} = ((\text{Emission limit} \times (Q_{ab}+Q_{cm}+Q_{ks})) - (Q_{ab} \times C_{ab}) - (Q_{cm} \times C_{cm}))/Q_{ks}$$

C_{ks} = Kiln stack concentration (ppmvd, mg dscm, ng/dscm, depending on pollutant. Each corrected to 7% O_2.)
Q_{ab} = Alkali bypass flow rate (volume/hr)
C_{ab} = Alkali bypass concentration (ppmvd, mg/dscm, ng/dscm, depending on pollutant. Each corrected to 7% O_2.)
Q_{cm} = In-line coal mill flow rate (volume/hr)
C_{cm} = In-line coal mill concentration (ppmvd, mg/dscm, ng/dscm, depending on pollutant. Each corrected to 7% O_2.)
Q_{ks} = Kiln stack flow rate (volume/hr)

(2) Particulate matter concentration must be measured downstream of the in-line coal mill. All other pollutant concentrations must be measured either upstream or downstream of the in-line coal mill; and

(3) For purposes of determining the combined emissions from kilns equipped with an alkali bypass or that exhaust kiln gases to a coal mill that exhausts through a separate stack, instead of installing a CEMS or PM CPMS on the alkali bypass stack or in-line coal mill stack, the results of the initial and subsequent performance test can be used to demonstrate compliance with the relevant emissions limit. A performance test must be conducted on an annual basis (between 11 and 13 calendar months following the previous performance test).

§ 60.2150 By what date must I conduct the annual performance test?

You must conduct annual performance tests between 11 and 13 months of the previous performance test.

§ 60.2151 By what date must I conduct the annual air pollution control device inspection?

On an annual basis (no more than 12 months following the previous annual air pollution control device inspection), you must complete the air pollution control device inspection as described in § 60.2141.

§ 60.2155 May I conduct performance testing less often?

(a) You must conduct annual performance tests according to the schedule specified in § 60.2150, with the following exceptions:

(1) You may conduct a repeat performance test at any time to establish new values for the operating limits to apply from that point forward, as specified in § 60.2160. The Administrator may request a repeat performance test at any time;

(2) You must repeat the performance test within 60 days of a process change, as defined in § 60.2265;

(3) If the initial or any subsequent performance test for any pollutant in table 1 or tables 5 through 8 of this subpart, as applicable, demonstrates that the emission level for the pollutant is no greater than the emission level specified in paragraph (a)(3)(i) or (a)(3)(ii) of this section, as

(i) For particulate matter, hydrogen chloride, mercury, nitrogen oxides, sulfur dioxide, cadmium, lead and dioxins/furans, the emission level equal to 75 percent of the applicable emission limit in table 1 or tables 5 through 8 of this subpart, as applicable, to this subpart; and

(ii) For fugitive emissions, visible emissions (of combustion ash from the ash conveying system) for 2 percent of the time during each of the three 1-hour observations periods.

(4) If you are conducting less frequent testing for a pollutant as provided in paragraph (a)(3) of this section and a subsequent performance test for the pollutant indicates that your CISWI unit does not meet the emission level specified in paragraph (a)(3)(i) or (a)(3)(ii) of this section, as applicable, you must conduct annual performance tests for the pollutant according to the schedule specified in paragraph (a) of this section until you qualify for less frequent testing for the pollutant as specified in paragraph (a)(3) of this section.

(b) [Reserved]

§ 60.2160 May I conduct a repeat performance test to establish new operating limits?

(a) Yes. You may conduct a repeat performance test at any time to establish new values for the operating limits. The Administrator may request a repeat performance test at any time.

(b) You must repeat the performance test if your feed stream is different than the feed streams used during any performance test used to demonstrate compliance.

Monitoring

§ 60.2165 What monitoring equipment must I install and what parameters must I monitor?

(a) If you are using a wet scrubber to comply with the emission limitation under § 60.2105, you must install, calibrate (to manufacturers' specifications), maintain, and operate devices (or establish methods) for monitoring the value of the operating parameters used to determine compliance with the operating limits listed in table 2 of this subpart. These devices (or methods) must measure and record the values for these operating parameters at the frequencies indicated in table 2 of this subpart at all times except as specified in § 60.2170(a).

(b) If you use a fabric filter to comply with the requirements of this subpart and you do not use a PM CPMS for monitoring PM compliance, you must install, calibrate, maintain, and continuously operate a bag leak detection system as specified in paragraphs (b)(1) through (8) of this section:

(1) You must install and operate a bag leak detection system for each exhaust stack of the fabric filter;

(2) Each bag leak detection system must be installed, operated, calibrated, and maintained in a manner consistent with the manufacturer's written specifications and recommendations;

(3) The bag leak detection system must be certified by the manufacturer to be capable of detecting particulate matter emissions at concentrations of 10 milligrams per actual cubic meter or less;

(4) The bag leak detection system sensor must provide output of relative or absolute particulate matter loadings;

(5) The bag leak detection system must be equipped with a device to continuously record the output signal from the sensor;

(6) The bag leak detection system must be equipped with an alarm system that will alert automatically an operator when an increase in relative particulate matter emissions over a preset level is detected. The alarm must be located where it is observed easily by plant operating personnel;

(7) For positive pressure fabric filter systems, a bag leak detection system must be installed in each baghouse compartment or cell. For negative pressure or induced air fabric filters, the bag leak detector must be installed downstream of the fabric filter; and

(8) Where multiple detectors are required, the system's instrumentation and alarm may be shared among detectors.

(c) If you are using something other than a wet scrubber, activated carbon, selective non-catalytic reduction, an electrostatic precipitator, or a dry scrubber to comply with the emission limitations under § 60.2105, you must install, calibrate (to the manufacturers' specifications), maintain, and operate the equipment necessary to monitor compliance with the site-specific operating limits established using the procedures in § 60.2115.

(d) If you use activated carbon injection to comply with the emission limitations in this subpart, you must measure the minimum mercury sorbent flow rate once per hour.

(e) If you use selective noncatalytic reduction to comply with the emission limitations, you must complete the following:

(1) Following the date on which the initial performance test is completed or is required to be completed under § 60.2125, whichever date comes first, ensure that the affected facility does not operate above the maximum charge rate, or below the minimum secondary chamber temperature (if applicable to your CISWI unit) or the minimum reagent flow rate measured as 3-hour block averages at all times; and

(2) Operation of the affected facility above the maximum charge rate, below the minimum secondary chamber temperature and below the minimum reagent flow rate simultaneously constitute a violation of the nitrogen oxides emissions limit.

(f) If you use an electrostatic precipitator to comply with the emission limits of this subpart and you do not use a PM CPMS for monitoring PM compliance, you must monitor the secondary power to the electrostatic precipitator collection plates and maintain the 3-hour block averages at or above the operating limits established during the mercury or particulate matter performance test.

(g) For waste-burning kilns not equipped with a wet scrubber or dry scrubber, in place of hydrogen chloride testing with EPA Method 321 at 40 CFR part 63, appendix A, an owner or operator must install, calibrate, maintain, and operate a CEMS for monitoring hydrogen chloride emissions, as specified in § 60.2145(j) of this subpart, discharged to the atmosphere and record the output of the system. To demonstrate continuous compliance with the hydrogen chloride emissions limit for units other than waste-burning kilns not equipped with a wet scrubber or dry scrubber, a facility may substitute use of a hydrogen chloride CEMS for conducting the hydrogen chloride annual performance test, monitoring the minimum hydrogen chloride sorbent flow rate, monitoring the minimum scrubber liquor pH, and monitoring minimum injection rate.

(h) To demonstrate continuous compliance with the particulate matter emissions limit, a facility may substitute use of either a particulate matter CEMS or a particulate matter CPMS for conducting the PM annual performance test and using other CMS for monitoring PM compliance (*e.g.,* bag leak detectors, ESP secondary power, PM scrubber pressure).

(i) To demonstrate continuous compliance with the dioxin/furan emissions limit, a facility may substitute use of a continuous automated sampling system for the dioxin/furan annual performance test. You must record the output of the system and analyze the sample according to EPA Method 23 at 40 CFR part 60, appendix A–7 of this part. This option to use a continuous automated sampling system takes effect on the date a final performance specification applicable to dioxin/furan from continuous monitors is published in the **Federal Register**. The owner or operator who elects to continuously sample dioxin/furan emissions instead of sampling and testing using EPA Method 23 at 40 CFR part 60, appendix A–7 must install, calibrate, maintain, and operate a continuous automated sampling system and must comply with the requirements specified in § 60.58b(p) and (q). A facility may substitute continuous dioxin/furan monitoring for the minimum sorbent flow rate, if activated carbon sorbent injection is used solely for compliance with the dioxin/furan emission limit.

(j) To demonstrate continuous compliance with the mercury emissions limit, a facility may substitute use of a continuous automated sampling system for the mercury annual performance test. You must record the output of the system and analyze the sample at set intervals using any suitable determinative technique that can meet performance specification 12B. The owner or operator who elects to continuously sample mercury emissions instead of sampling and testing using EPA Reference Method 29 or 30B at 40 CFR part 60, appendix A–8, ASTM D6784–02 (Reapproved 2008) (incorporated by reference, see § 60.17), or an approved alternative method for measuring mercury emissions, must install, calibrate, maintain, and operate a continuous automated sampling system and must comply with performance specification 12A and quality assurance procedure 5, as well as the requirements specified in § 60.58b(p) and (q). A facility may substitute continuous mercury monitoring for the minimum sorbent flow rate, if activated carbon sorbent injection is used solely for compliance with the mercury emission limit. Waste-burning kilns must install, calibrate, maintain, and operate a mercury CEMS as specified in § 60.2145(j).

(k) To demonstrate continuous compliance with the nitrogen oxides emissions limit, a facility may substitute use of a CEMS for the nitrogen oxides annual performance test to demonstrate compliance with the nitrogen oxides emissions limits and monitoring the charge rate, secondary chamber temperature, and reagent flow for selective noncatalytic reduction, if applicable:

(1) Install, calibrate, maintain, and operate a CEMS for measuring nitrogen oxides emissions discharged to the atmosphere and record the output of the system. The requirements under performance specification 2 of appendix B of this part, the quality assurance

procedure one of appendix F of this part and the procedures under § 60.13 must be followed for installation, evaluation, and operation of the CEMS; and

(2) Following the date that the initial performance test for nitrogen oxides is completed or is required to be completed under § 60.2125, compliance with the emission limit for nitrogen oxides required under § 60.52b(d) must be determined based on the 30-day rolling average of the hourly emission concentrations using CEMS outlet data. The 1-hour arithmetic averages must be expressed in parts per million by volume corrected to 7 percent oxygen (dry basis) and used to calculate the 30-day rolling average concentrations. CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content. The 1-hour arithmetic averages must be calculated using the data points required under § 60.13(e)(2).

(l) To demonstrate continuous compliance with the sulfur dioxide emissions limit, a facility may substitute use of a continuous automated sampling system for the sulfur dioxide annual performance test to demonstrate compliance with the sulfur dioxide emissions limits:

(1) Install, calibrate, maintain, and operate a CEMS for measuring sulfur dioxide emissions discharged to the atmosphere and record the output of the system. The requirements under performance specification 2 of appendix B of this part, the quality assurance requirements of procedure one of appendix F of this part and procedures under § 60.13 must be followed for installation, evaluation, and operation of the CEMS; and

(2) Following the date that the initial performance test for sulfur dioxide is completed or is required to be completed under § 60.2125, compliance with the sulfur dioxide emission limit may be determined based on the 30-day rolling average of the hourly arithmetic average emission concentrations using CEMS outlet data. The 1-hour arithmetic averages must be expressed in parts per million corrected to 7 percent oxygen (dry basis) and used to calculate the 30-day rolling average emission concentrations. CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content. The 1-hour arithmetic averages must be calculated using the data points required under § 60.13(e)(2).

(m) For energy recovery units over 10 MMBtu/hr but less than 250 MMBtu/hr annual average heat input rates that do not use a wet scrubber, fabric filter with bag leak detection system, or particulate matter CEMS, you must install, operate, certify, and maintain a continuous opacity monitoring system according to the procedures in paragraphs (m)(1) through (5) of this section by the compliance date specified in § 60.2105. Energy recovery units that use a CEMS to demonstrate initial and continuing compliance according to the procedures in § 60.2165(n) are not required to install a continuous opacity monitoring system and must perform the annual performance tests for the opacity consistent with § 60.2145(f):

(1) Install, operate, and maintain each continuous opacity monitoring system according to performance specification 1 of 40 CFR part 60, appendix B;

(2) Conduct a performance evaluation of each continuous opacity monitoring system according to the requirements in § 60.13 and according to PS–1 of 40 CFR part 60, appendix B;

(3) As specified in § 60.13(e)(1), each continuous opacity monitoring system must complete a minimum of one cycle of sampling and analyzing for each successive 10-second period and one cycle of data recording for each successive 6-minute period;

(4) Reduce the continuous opacity monitoring system data as specified in § 60.13(h)(1); and

(5) Determine and record all the 6-minute averages (and 1-hour block averages as applicable) collected.

(n) For coal and liquid/gas energy recovery units, incinerators, and small remote incinerators, an owner or operator may elect to install, calibrate, maintain, and operate a CEMS for monitoring particulate matter emissions discharged to the atmosphere and record the output of the system. The owner or operator of an affected facility who continuously monitors particulate matter emissions instead of conducting performance testing using EPA Method 5 at 40 CFR part 60, appendix A–3 or, as applicable, monitor with a particulate matter CPMS according to paragraph (r) of this section, must install, calibrate, maintain, and operate a CEMS and must comply with the requirements specified in paragraphs (n)(1) through (13) of this section:

(1) Notify the Administrator 1 month before starting use of the system;

(2) Notify the Administrator 1 month before stopping use of the system;

(3) The monitor must be installed, evaluated, and operated in accordance with the requirements of performance specification 11 of appendix B of this part and quality assurance requirements of procedure two of appendix F of this part and § 60.13. Use Method 5 or Method 5I of Appendix A of this part for the PM CEMS correlation testing;

(4) The initial performance evaluation must be completed no later than 180 days after the date of initial startup of the affected facility, as specified under § 60.2125 or within 180 days of notification to the Administrator of use of the continuous monitoring system if the owner or operator was previously determining compliance by Method 5 performance tests, whichever is later;

(5) The owner or operator of an affected facility may request that compliance with the particulate matter emission limit be determined using carbon dioxide measurements corrected to an equivalent of 7 percent oxygen. The relationship between oxygen and carbon dioxide levels for the affected facility must be established according to the procedures and methods specified in § 60.2145(t)(4)(i) through (iv);

(6) The owner or operator of an affected facility must conduct an initial performance test for particulate matter emissions as required under § 60.2125. Compliance with the particulate matter emission limit, if PM CEMS are elected for demonstrating compliance, must be determined by using the CEMS specified in paragraph (n) of this section to measure particulate matter. You must calculate a 30-day rolling average of 1-hour arithmetic average emission concentrations, including CEMS data during startup and shutdown, as defined in this subpart, using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, appendix A–7;

(7) Compliance with the particulate matter emission limit must be determined based on the 30-day rolling average calculated using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, appendix A–7 from the 1-hour arithmetic average CEMS outlet data;

(8) At a minimum, valid continuous monitoring system hourly averages must be obtained as specified in § 60.2170(e);

(9) The 1-hour arithmetic averages required under paragraph (n)(7) of this section must be expressed in milligrams per dry standard cubic meter corrected to 7 percent oxygen (dry basis) and must be used to calculate the 30-day rolling average emission concentrations. CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content. The 1-hour arithmetic averages must be calculated using the data points required under § 60.13(e)(2);

(10) All valid CEMS data must be used in calculating average emission concentrations even if the minimum

CEMS data requirements of paragraph (n)(8) of this section are not met.

(11) The CEMS must be operated according to performance specification 11 in appendix B of this part;

(12) During each relative accuracy test run of the CEMS required by performance specification 11 in appendix B of this part, particulate matter and oxygen (or carbon dioxide) data must be collected concurrently (or within a 30- to 60-minute period) by both the CEMS and the following test methods:

(i) For particulate matter, EPA Reference Method 5 must be used; and

(ii) For oxygen (or carbon dioxide), EPA Reference Method 3A or 3B, as applicable, must be used; and

(13) Quarterly accuracy determinations and daily calibration drift tests must be performed in accordance with procedure 2 in appendix F of this part.

(o) To demonstrate continuous compliance with the carbon monoxide emissions limit, you may substitute use of a continuous automated sampling system for the carbon monoxide annual performance test:

(1) Install, calibrate, maintain, and operate a CEMS for measuring carbon monoxide emissions discharged to the atmosphere and record the output of the system. The requirements under performance specification 4B of appendix B of this part, the quality assurance procedure 1 of appendix F of this part and the procedures under § 60.13 must be followed for installation, evaluation, and operation of the CEMS; and

(2) Following the date that the initial performance test for carbon monoxide is completed or is required to be completed under § 60.2140, compliance with the carbon monoxide emission limit may be determined based on the 30-day rolling average of the hourly arithmetic average emission concentrations, including CEMS data during startup and shutdown as defined in this subpart, using CEMS outlet data. Except for CEMS data during startup and shutdown, as defined in this subpart, the 1-hour arithmetic averages must be expressed in parts per million corrected to 7 percent oxygen (dry basis) and used to calculate the 30-day rolling average emission concentrations. CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content. The 1-hour arithmetic averages must be calculated using the data points required under § 60.13(e)(2).

(p) The owner/operator of an affected source with a bypass stack shall install, calibrate (to manufacturers' specifications), maintain, and operate a device or method for measuring the use of the bypass stack including date, time and duration.

(q) For energy recovery units with a design heat input capacity of 100 MMBtu per hour or greater that do not use a carbon monoxide CEMS, you must install, operate, and maintain a oxygen analyzer system as defined in § 60.2265 according to the procedures in paragraphs (q)(1) through (4) of this section:

(1) The oxygen analyzer system must be installed by the initial performance test date specified in § 60.2140;

(2) You must operate the oxygen trim system within compliance with paragraph (q)(3) of this section at all times;

(3) You must maintain the oxygen level such that the 30-day rolling average that is established as the operating limit for oxygen according to paragraph (q)(4) of this section is not below the lowest hourly average oxygen concentration measured during the most recent CO performance test; and

(4) You must calculate and record a 30-day rolling average oxygen concentration using equation 19–19 in section 12.4.1 of EPA Reference Method 19 of Appendix A–7 of this part.

(r) For energy recovery units with annual average heat input rates greater than or equal to 250 MMBtu/hour and waste-burning kilns, you must install, calibrate, maintain, and operate a PM CPMS and record the output of the system as specified in paragraphs (r)(1) through (8) of this section. If you elect to use a particulate matter CEMS as specified in paragraph (n) of this section, you are not required to use a PM CPMS to monitor particulate matter emissions. For other energy recovery units, you may elect to use PM CPMS operated in accordance with this section. PM CPMS are suitable in lieu of using other CMS for monitoring PM compliance (*e.g.,* bag leak detectors, ESP secondary power, PM scrubber pressure):

(1) Install, calibrate, operate, and maintain your PM CPMS according to the procedures in your approved site-specific monitoring plan developed in accordance with § 60.2145(l) and (r)(1)(i) through (iii) of this section:

(i) The operating principle of the PM CPMS must be based on in-stack or extractive light scatter, light scintillation, beta attenuation, or mass accumulation detection of PM in the exhaust gas or representative sample. The reportable measurement output from the PM CPMS must be expressed as milliamps or a digital signal equivalent;

(ii) The PM CPMS must have a cycle time (*i.e.,* period required to complete sampling, measurement, and reporting for each measurement) no longer than 60 minutes; and

(iii) The PM CPMS must be capable of detecting and responding to particulate matter concentration increments no greater than 0.5 mg/actual cubic meter.

(2) During the initial performance test or any such subsequent performance test that demonstrates compliance with the PM limit, you must adjust the site-specific operating limit in accordance with the results of the performance test according to the procedures specified in § 60.2110.

(3) Collect PM CPMS hourly average output data for all energy recovery unit or waste-burning kiln operating hours. Express the PM CPMS output as milliamps or the digital signal equivalent.

(4) Calculate the arithmetic 30-day rolling average of all of the hourly average PM CPMS output collected during all energy recovery unit or waste-burning kiln operating hours data (milliamps or digital bits).

(5) You must collect data using the PM CPMS at all times the energy recovery unit or waste-burning kiln is operating and at the intervals specified in paragraph (r)(1)(ii) of this section, except for periods of monitoring system malfunctions, repairs associated with monitoring system malfunctions, required monitoring system quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments), and any scheduled maintenance as defined in your site-specific monitoring plan.

(6) You must use all the data collected during all energy recovery unit or waste-burning kiln operating hours in assessing the compliance with your operating limit except:

(i) Any data collected during monitoring system malfunctions, repairs associated with monitoring system malfunctions, or required monitoring system quality assurance or quality control activities conducted during monitoring system malfunctions are not used in calculations (report any such periods in your annual deviation report);

(ii) Any data collected during periods when the monitoring system is out of control as specified in your site-specific monitoring plan, repairs associated with periods when the monitoring system is out of control, or required monitoring system quality assurance or quality control activities conducted during out-of-control periods are not used in calculations (report emissions or operating levels and report any such periods in your annual deviation report); and

(iii) Any PM CPMS data recorded during periods of CEMS data during startup and shutdown, as defined in this subpart.

(7) You must record and make available upon request results of PM CPMS system performance audits, as well as the dates and duration of periods from when the PM CPMS is out of control until completion of the corrective actions necessary to return the PM CPMS to operation consistent with your site-specific monitoring plan.

(8) For any deviation of the 30-day rolling average PM CPMS average value from the established operating parameter limit, you must:

(i) Within 48 hours of the deviation, visually inspect the air pollution control device;

(ii) If inspection of the air pollution control device identifies the cause of the deviation, take corrective action as soon as possible and return the PM CPMS measurement to within the established value;

(iii) Within 30 days of the deviation or at the time of the annual compliance test, whichever comes first, conduct a PM emissions compliance test to determine compliance with the PM emissions limit and to verify the operation of the emissions control device(s). Within 45 days of the deviation, you must re-establish the CPMS operating limit. You are not required to conduct additional testing for any deviations that occur between the time of the original deviation and the PM emissions compliance test required under this paragraph; and

(iv) PM CPMS deviations leading to more than four required performance tests in a 12-month process operating period (rolling monthly) constitute a violation of this subpart.

(s) If you use a dry scrubber to comply with the emission limits of this subpart, you must monitor the injection rate of each sorbent and maintain the 3-hour block averages at or above the operating limits established during the hydrogen chloride performance test.

§ 60.2170 Is there a minimum amount of monitoring data I must obtain?

For each continuous monitoring system required or optionally allowed under § 60.2165, you must collect data according to this section:

(a) You must operate the monitoring system and collect data at all required intervals at all times compliance is required except for periods of monitoring system malfunctions or out-of-control periods, repairs associated with monitoring system malfunctions or out-of-control periods (as specified in 60.2210(o)), and required monitoring system quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments). A monitoring system malfunction is any sudden, infrequent, not reasonably preventable failure of the monitoring system to provide valid data. Monitoring system failures that are caused in part by poor maintenance or careless operation are not malfunctions. You are required to effect monitoring system repairs in response to monitoring system malfunctions or out-of-control periods and to return the monitoring system to operation as expeditiously as practicable;

(b) You may not use data recorded during monitoring system malfunctions or out-of-control periods, repairs associated with monitoring system malfunctions or out-of-control periods, or required monitoring system quality assurance or control activities in calculations used to report emissions or operating levels. You must use all the data collected during all other periods, including data normalized for above scale readings, in assessing the operation of the control device and associated control system; and

(c) Except for periods of monitoring system malfunctions or out-of-control periods, repairs associated with monitoring system malfunctions or out-of-control periods, and required monitoring system quality assurance or quality control activities including, as applicable, calibration checks and required zero and span adjustments, failure to collect required data is a deviation of the monitoring requirements.

Recordkeeping and Reporting

§ 60.2175 What records must I keep?

You must maintain the items (as applicable) as specified in paragraphs (a), (b), and (e) through (x) of this section for a period of at least 5 years:

(a) Calendar date of each record; and

(b) Records of the data described in paragraphs (b)(1) through (6) of this section:

(1) The CISWI unit charge dates, times, weights, and hourly charge rates;

(2) Liquor flow rate to the wet scrubber inlet every 15 minutes of operation, as applicable;

(3) Pressure drop across the wet scrubber system every 15 minutes of operation or amperage to the wet scrubber every 15 minutes of operation, as applicable;

(4) Liquor pH as introduced to the wet scrubber every 15 minutes of operation, as applicable;

(5) For affected CISWI units that establish operating limits for controls other than wet scrubbers under § 60.2110(d) through (g) or § 60.2115, you must maintain data collected for all operating parameters used to determine compliance with the operating limits. For energy recovery units using activated carbon injection or a dry scrubber, you must also maintain records of the load fraction and corresponding sorbent injection rate records;

(6) If a fabric filter is used to comply with the emission limitations, you must record the date, time, and duration of each alarm and the time corrective action was initiated and completed, and a brief description of the cause of the alarm and the corrective action taken. You must also record the percent of operating time during each 6-month period that the alarm sounds, calculated as specified in § 60.2110(c);

(c)–(d) [Reserved]

(e) Identification of calendar dates and times for which data show a deviation from the operating limits in table 2 of this subpart or a deviation from other operating limits established under § 60.2110(d) through (g) or § 60.2115 with a description of the deviations, reasons for such deviations, and a description of corrective actions taken;

(f) The results of the initial, annual, and any subsequent performance tests conducted to determine compliance with the emission limits and/or to establish operating limits, as applicable. Retain a copy of the complete test report including calculations;

(g) All documentation produced as a result of the siting requirements of §§ 60.2045 and 60.2050;

(h) Records showing the names of CISWI unit operators who have completed review of the information in § 60.2095(a) as required by § 60.2095(b), including the date of the initial review and all subsequent annual reviews;

(i) Records showing the names of the CISWI operators who have completed the operator training requirements under § 60.2070, met the criteria for qualification under § 60.2080, and maintained or renewed their qualification under § 60.2085 or § 60.2090. Records must include documentation of training, the dates of the initial and refresher training, and the dates of their qualification and all subsequent renewals of such qualifications;

(j) For each qualified operator, the phone and/or pager number at which they can be reached during operating hours;

(k) Records of calibration of any monitoring devices as required under § 60.2165;

(l) Equipment vendor specifications and related operation and maintenance requirements for the incinerator, emission controls, and monitoring equipment;

(m) The information listed in § 60.2095(a);

(n) On a daily basis, keep a log of the quantity of waste burned and the types of waste burned (always required);

(o) Maintain records of the annual air pollution control device inspections that are required for each CISWI unit subject to the emissions limits in table 1 of this subpart or tables 5 through 8 of this subpart, any required maintenance, and any repairs not completed within 10 days of an inspection or the timeframe established by the state regulatory agency;

(p) For continuously monitored pollutants or parameters, you must document and keep a record of the following parameters measured using continuous monitoring systems:

(1) All 6-minute average levels of opacity;

(2) All 1-hour average concentrations of sulfur dioxide emissions;

(3) All 1-hour average concentrations of nitrogen oxides emissions;

(4) All 1-hour average concentrations of carbon monoxide emissions. You must indicate which data are CEMS data during startup and shutdown;

(5) All 1-hour average concentrations of particulate matter emissions;

(6) All 1-hour average concentrations of mercury emissions;

(7) All 1-hour average concentrations of hydrogen chloride emissions;

(8) All 1-hour average percent oxygen concentrations; and

(9) All 1-hour average PM CPMS readings or particulate matter CEMS outputs;

(q) Records indicating use of the bypass stack, including dates, times, and durations.

(r) If you choose to stack test less frequently than annually, consistent with § 60.2155(a) through (c), you must keep annual records that document that your emissions in the previous stack test(s) were less than 75 percent of the applicable emission limit and document that there was no change in source operations including fuel composition and operation of air pollution control equipment that would cause emissions of the relevant pollutant to increase within the past year.

(s) Records of the occurrence and duration of each malfunction of operation (*i.e.,* process equipment) or the air pollution control and monitoring equipment.

(t) Records of all required maintenance performed on the air pollution control and monitoring equipment.

(u) Records of actions taken during periods of malfunction to minimize emissions in accordance with § 60.11(d), including corrective actions to restore malfunctioning process and air pollution control and monitoring equipment to its normal or usual manner of operation.

(v) For operating units that combust non-hazardous secondary materials that have been determined not to be solid waste pursuant to § 241.3(b)(1) of this chapter, you must keep a record which documents how the secondary material meets each of the legitimacy criteria under § 241.3(d)(1). If you combust a fuel that has been processed from a discarded non-hazardous secondary material pursuant to § 241.3(b)(4) of this chapter, you must keep records as to how the operations that produced the fuel satisfies the definition of processing in § 241.2 and each of the legitimacy criteria of § 241.3(d)(1) of this chapter. If the fuel received a non-waste determination pursuant to the petition process submitted under § 241.3(c) of this chapter, you must keep a record that documents how the fuel satisfies the requirements of the petition process. For operating units that combust non-hazardous secondary materials as fuel per § 241.4, you must keep records documenting that the material is a listed non-waste under § 241.4(a).

(w) Records of the criteria used to establish that the unit qualifies as a small power production facility under section 3(17)(C) of the Federal Power Act (16 U.S.C. 796(17)(C)) and that the waste material the unit is proposed to burn is homogeneous.

(x) Records of the criteria used to establish that the unit qualifies as a cogeneration facility under section 3(18)(B) of the Federal Power Act (16 U.S.C. 796(18)(B)) and that the waste material the unit is proposed to burn is homogeneous.

§ 60.2180 Where and in what format must I keep my records?

All records must be available onsite in either paper copy or computer-readable format that can be printed upon request, unless an alternative format is approved by the Administrator.

§ 60.2185 What reports must I submit?

See table 4 of this subpart for a summary of the reporting requirements.

§ 60.2190 What must I submit prior to commencing construction?

You must submit a notification prior to commencing construction that includes the five items listed in paragraphs (a) through (e) of this section:

(a) A statement of intent to construct;

(b) The anticipated date of commencement of construction;

(c) All documentation produced as a result of the siting requirements of § 60.2050;

(d) The waste management plan as specified in §§ 60.2055 through 60.2065; and

(e) Anticipated date of initial startup.

§ 60.2195 What information must I submit prior to initial startup?

You must submit the information specified in paragraphs (a) through (e) of this section prior to initial startup:

(a) The type(s) of waste to be burned;

(b) The maximum design waste burning capacity;

(c) The anticipated maximum charge rate;

(d) If applicable, the petition for site-specific operating limits under § 60.2115; and

(e) The anticipated date of initial startup.

§ 60.2200 What information must I submit following my initial performance test?

You must submit the information specified in paragraphs (a) through (c) of this section no later than 60 days following the initial performance test. All reports must be signed by the facilities manager:

(a) The complete test report for the initial performance test results obtained under § 60.2135, as applicable;

(b) The values for the site-specific operating limits established in § 60.2110 or § 60.2115; and

(c) If you are using a fabric filter to comply with the emission limitations, documentation that a bag leak detection system has been installed and is being operated, calibrated, and maintained as required by § 60.2165(b).

§ 60.2205 When must I submit my annual report?

You must submit an annual report no later than 12 months following the submission of the information in § 60.2200. You must submit subsequent reports no more than 12 months following the previous report. (If the unit is subject to permitting requirements under title V of the Clean Air Act, you may be required by the permit to submit these reports more frequently.)

§ 60.2210 What information must I include in my annual report?

The annual report required under § 60.2205 must include the ten items listed in paragraphs (a) through (j) of this section. If you have a deviation from the operating limits or the emission limitations, you must also submit deviation reports as specified in §§ 60.2215, 60.2220, and 60.2225:

(a) Company name and address;

(b) Statement by a responsible official, with that official's name, title, and signature, certifying the accuracy of the content of the report;

(c) Date of report and beginning and ending dates of the reporting period;

(d) The values for the operating limits established pursuant to § 60.2110 or § 60.2115;

(e) If no deviation from any emission limitation or operating limit that applies to you has been reported, a statement that there was no deviation from the emission limitations or operating limits during the reporting period;

(f) The highest recorded 3-hour average and the lowest recorded 3-hour average, as applicable, for each operating parameter recorded for the calendar year being reported;

(g) Information recorded under § 60.2175(b)(6) and (c) through (e) for the calendar year being reported;

(h) For each performance test conducted during the reporting period, if any performance test is conducted, the process unit(s) tested, the pollutant(s) tested and the date that such performance test was conducted. Submit, following the procedure specified in § 60.2235(b)(1), the performance test report no later than the date that you submit the annual report;

(i) If you met the requirements of § 60.2155(a) or (b), and did not conduct a performance test during the reporting period, you must state that you met the requirements of § 60.2155(a) or (b), and, therefore, you were not required to conduct a performance test during the reporting period;

(j) Documentation of periods when all qualified CISWI unit operators were unavailable for more than 8 hours, but less than 2 weeks;

(k) If you had a malfunction during the reporting period, the compliance report must include the number, duration, and a brief description for each type of malfunction that occurred during the reporting period and that caused or may have caused any applicable emission limitation to be exceeded. The report must also include a description of actions taken by an owner or operator during a malfunction of an affected source to minimize emissions in accordance with § 60.11(d), including actions taken to correct a malfunction;

(l) For each deviation from an emission or operating limitation that occurs for a CISWI unit for which you are not using a continuous monitoring system to comply with the emission or operating limitations in this subpart, the annual report must contain the following information:

(1) The total operating time of the CISWI unit at which the deviation occurred during the reporting period; and

(2) Information on the number, duration, and cause of deviations (including unknown cause, if applicable), as applicable, and the corrective action taken.

(m) If there were periods during which the continuous monitoring system, including the CEMS, was out of control as specified in paragraph (o) of this section, the annual report must contain the following information for each deviation from an emission or operating limitation occurring for a CISWI unit for which you are using a continuous monitoring system to comply with the emission and operating limitations in this subpart:

(1) The date and time that each malfunction started and stopped;

(2) The date, time, and duration that each CMS was inoperative, except for zero (low-level) and high-level checks;

(3) The date, time, and duration that each continuous monitoring system was out-of-control, including start and end dates and hours and descriptions of corrective actions taken;

(4) The date and time that each deviation started and stopped, and whether each deviation occurred during a period of malfunction or during another period;

(5) A summary of the total duration of the deviation during the reporting period, and the total duration as a percent of the total source operating time during that reporting period;

(6) A breakdown of the total duration of the deviations during the reporting period into those that are due to control equipment problems, process problems, other known causes, and other unknown causes;

(7) A summary of the total duration of continuous monitoring system downtime during the reporting period, and the total duration of continuous monitoring system downtime as a percent of the total operating time of the CISWI unit at which the continuous monitoring system downtime occurred during that reporting period;

(8) An identification of each parameter and pollutant that was monitored at the CISWI unit;

(9) A brief description of the CISWI unit;

(10) A brief description of the continuous monitoring system;

(11) The date of the latest continuous monitoring system certification or audit; and

(12) A description of any changes in continuous monitoring system, processes, or controls since the last reporting period.

(n) If there were periods during which the continuous monitoring system, including the CEMS, was not out of control as specified in paragraph (o) of this section, a statement that there were not periods during which the continuous monitoring system was out of control during the reporting period.

(o) A continuous monitoring system is out of control in accordance with the procedure in 40 CFR part 60, appendix F of this part, as if any of the following occur:

(1) The zero (low-level), mid-level (if applicable), or high-level calibration drift exceeds two times the applicable calibration drift specification in the applicable performance specification or in the relevant standard;

(2) The continuous monitoring system fails a performance test audit (*e.g.,* cylinder gas audit), relative accuracy audit, relative accuracy test audit, or linearity test audit; and

(3) The continuous opacity monitoring system calibration drift exceeds two times the limit in the applicable performance specification in the relevant standard.

§ 60.2215 What else must I report if I have a deviation from the operating limits or the emission limitations?

(a) You must submit a deviation report if any recorded 3-hour average parameter level is above the maximum operating limit or below the minimum operating limit established under this subpart, if the bag leak detection system alarm sounds for more than 5 percent of the operating time for the 6-month reporting period, or if a performance test was conducted that deviated from any emission limitation.

(b) The deviation report must be submitted by August 1 of that year for data collected during the first half of the calendar year (January 1 to June 30), and by February 1 of the following year for data you collected during the second half of the calendar year (July 1 to December 31).

§ 60.2220 What must I include in the deviation report?

In each report required under § 60.2215, for any pollutant or parameter that deviated from the emission limitations or operating limits specified in this subpart, include the six items described in paragraphs (a) through (f) of this section:

(a) The calendar dates and times your unit deviated from the emission limitations or operating limit requirements;

(b) The averaged and recorded data for those dates;

(c) Durations and causes of the following:

(1) Each deviation from emission limitations or operating limits and your corrective actions;

(2) Bypass events and your corrective actions; and

(d) A copy of the operating limit monitoring data during each deviation and for any test report that documents the emission levels the process unit(s) tested, the pollutant(s) tested and the date that the performance test was conducted. Submit, following the procedure specified in § 60.2235(b)(1), the performance test report no later than the date that you submit the deviation report.

§ 60.2225 What else must I report if I have a deviation from the requirement to have a qualified operator accessible?

(a) If all qualified operators are not accessible for 2 weeks or more, you must take the two actions in paragraphs (a)(1) and (2) of this section:

(1) Submit a notification of the deviation within 10 days that includes the three items in paragraphs (a)(1)(i) through (iii) of this section:

(i) A statement of what caused the deviation;

(ii) A description of what you are doing to ensure that a qualified operator is accessible; and

(iii) The date when you anticipate that a qualified operator will be available.

(2) Submit a status report to the Administrator every 4 weeks that includes the three items in paragraphs (a)(2)(i) through (iii) of this section:

(i) A description of what you are doing to ensure that a qualified operator is accessible;

(ii) The date when you anticipate that a qualified operator will be accessible; and

(iii) Request approval from the Administrator to continue operation of the CISWI unit.

(b) If your unit was shut down by the Administrator, under the provisions of § 60.2100(b)(2), due to a failure to provide an accessible qualified operator, you must notify the Administrator that you are resuming operation once a qualified operator is accessible.

§ 60.2230 Are there any other notifications or reports that I must submit?

(a) Yes. You must submit notifications as provided by § 60.7.

(b) If you cease combusting solid waste but continue to operate, you must provide 30 days prior notice of the effective date of the waste-to-fuel switch, consistent with 60.2145(a). The notification must identify:

(1) The name of the owner or operator of the CISWI unit, the location of the source, the emissions unit(s) that will cease burning solid waste, and the date of the notice;

(2) The currently applicable subcategory under this subpart, and any 40 CFR part 63 subpart and subcategory that will be applicable after you cease combusting solid waste;

(3) The fuel(s), non-waste material(s) and solid waste(s) the CISWI unit is currently combusting and has combusted over the past 6 months, and the fuel(s) or non-waste materials the unit will commence combusting;

(4) The date on which you became subject to the currently applicable emission limits; and

(5) The date upon which you will cease combusting solid waste, and the date (if different) that you intend for any new requirements to become applicable (*i.e.*, the effective date of the waste-to-fuel switch), consistent with paragraphs (b)(2) and (3) of this section.

§ 60.2235 In what form can I submit my reports?

(a) Submit initial, annual and deviation reports electronically on or before the submittal due dates. Submit the reports to the EPA via the Compliance and Emissions Data Reporting Interface (CEDRI). (CEDRI can be accessed through the EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov/*).) Use the appropriate electronic report in CEDRI for this subpart or an alternate electronic file format consistent with the extensible markup language (XML) schema listed on the CEDRI Web site (*https://www3.epa.gov/ttn/chief/cedri/index.html*). If the reporting form specific to this subpart is not available in CEDRI at the time that the report is due, submit the report to the Administrator at the appropriate address listed in § 60.4. Once the form has been available in CEDRI for 90 calendar days, you must begin submitting all subsequent reports via CEDRI. The reports must be submitted by the deadlines specified in this subpart, regardless of the method in which the report is submitted.

(b) Submit results of each performance test and CEMS performance evaluation required by this subpart as follows:

(1) Within 60 days after the date of completing each performance test (*see* § 60.8) required by this subpart, you must submit the results of the performance test following the procedure specified in either paragraph (b)(1)(i) or (b)(1)(ii) of this section:

(i) For data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT Web site (*https://www3.epa.gov/ttn/chief/ert/ert_info.html*) at the time of the test, you must submit the results of the performance test to the EPA via the CEDRI. (CEDRI can be accessed through the EPA's CDX (*https://cdx.epa.gov/*).) Performance test data must be submitted in a file format generated through the use of the EPA's ERT or an alternate electronic file format consistent with the XML schema listed on the EPA's ERT Web site. If you claim that some of the performance test information being submitted is confidential business information (CBI), you must submit a complete file generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT Web site, including information claimed to be CBI, on a compact disc, flash drive, or other commonly used electronic storage media to the EPA. The electronic media must be clearly marked as CBI and mailed to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404-02, 4930 Old Page Rd., Durham, NC 27703. The same ERT or alternate file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph; and

(ii) For data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT Web site at the time of the test, you must submit the results of the performance test to the Administrator at the appropriate address listed in § 60.4.

(2) Within 60 days after the date of completing each continuous emissions monitoring system performance evaluation you must submit the results of the performance evaluation following the procedure specified in either paragraph (b)(2)(i) or (b)(2)(ii) of this section:

(i) For performance evaluations of continuous monitoring systems measuring relative accuracy test audit (RATA) pollutants that are supported by the EPA's ERT as listed on the EPA's ERT Web site at the time of the evaluation, you must submit the results of the performance evaluation to the EPA via the CEDRI. (CEDRI can be accessed through the EPA's CDX.) Performance evaluation data must be submitted in a file format generated through the use of the EPA's ERT or an alternate file format consistent with the XML schema listed on the EPA's ERT Web site. If you claim that some of the performance evaluation information being submitted is CBI, you must submit a complete file generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT Web site, including information claimed to be CBI, on a compact disc, flash drive, or other commonly used electronic storage media to the EPA. The electronic storage media must be clearly marked as CBI and mailed to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same ERT or alternate file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph; and

(ii) For any performance evaluations of continuous monitoring systems measuring RATA pollutants that are not supported by the EPA's ERT as listed on the EPA's ERT Web site at the time of the evaluation, you must submit the results of the performance evaluation to the Administrator at the appropriate address listed in § 60.4.

§ 60.2240 Can reporting dates be changed?

If the Administrator agrees, you may change the semiannual or annual reporting dates. See § 60.19(c) for procedures to seek approval to change your reporting date.

Title V Operating Permits

§ 60.2242 Am I required to apply for and obtain a Title V operating permit for my unit?

Yes. Each CISWI unit and air curtain incinerator subject to standards under this subpart must operate pursuant to a permit issued under Section 129(e) and Title V of the Clean Air Act.

Air Curtain Incinerators

§ 60.2245 What is an air curtain incinerator?

(a) An air curtain incinerator operates by forcefully projecting a curtain of air across an open chamber or open pit in which combustion occurs. Incinerators of this type can be constructed above or below ground and with or without refractory walls and floor. (Air curtain incinerators are not to be confused with conventional combustion devices with enclosed fireboxes and controlled air technology such as mass burn, modular, and fluidized bed combustors.)

(b) Air curtain incinerators that burn only the materials listed in paragraphs (b)(1) through (3) of this section are only required to meet the requirements under § 60.2242 and under "Air Curtain Incinerators" (§§ 60.2245 through 60.2260):

(1) 100 percent wood waste;

(2) 100 percent clean lumber; and

(3) 100 percent mixture of only wood waste, clean lumber, and/or yard waste.

§ 60.2250 What are the emission limitations for air curtain incinerators?

Within 60 days after your air curtain incinerator reaches the charge rate at which it will operate, but no later than 180 days after its initial startup, you must meet the two limitations specified in paragraphs (a) and (b) of this section:

(a) Maintain opacity to less than or equal to 10 percent opacity (as determined by the average of three 1-hour blocks consisting of ten 6-minute average opacity values), except as described in paragraph (b) of this section; and

(b) Maintain opacity to less than or equal to 35 percent opacity (as determined by the average of three 1-hour blocks consisting of ten 6-minute average opacity values) during the startup period that is within the first 30 minutes of operation.

§ 60.2255 How must I monitor opacity for air curtain incinerators?

(a) Use Method 9 of appendix A of this part to determine compliance with the opacity limitation.

(b) Conduct an initial test for opacity as specified in § 60.8.

(c) After the initial test for opacity, conduct annual tests no more than 12 calendar months following the date of your previous test.

§ 60.2260 What are the recordkeeping and reporting requirements for air curtain incinerators?

(a) Prior to commencing construction on your air curtain incinerator, submit the three items described in paragraphs (a)(1) through (3) of this section:

(1) Notification of your intent to construct the air curtain incinerators;

(2) Your planned initial startup date; and

(3) Types of materials you plan to burn in your air curtain incinerator.

(b) Keep records of results of all initial and annual opacity tests onsite in either paper copy or electronic format, unless the Administrator approves another format, for at least 5 years.

(c) Make all records available for submittal to the Administrator or for an inspector's onsite review.

(d) You must submit the results (as determined by the average of three 1-hour blocks consisting of ten 6-minute average opacity values) of the initial opacity tests no later than 60 days following the initial test. Submit annual opacity test results within 12 months following the previous report.

(e) Submit initial and annual opacity test reports as electronic or paper copy on or before the applicable submittal date.

(f) Keep a copy of the initial and annual reports onsite for a period of 5 years.

Definitions

§ 60.2265 What definitions must I know?

Terms used but not defined in this subpart are defined in the Clean Air Act and subpart A (General Provisions) of this part.

30-day rolling average means the arithmetic mean of the previous 720 hours of valid operating data. Valid data excludes periods when this unit is not operating. The 720 hours should be consecutive, but not necessarily continuous if operations are intermittent.

Administrator means the Administrator of the U.S. Environmental Protection Agency or his/her authorized representative or Administrator of a State Air Pollution Control Agency.

Air curtain incinerator means an incinerator that operates by forcefully projecting a curtain of air across an open chamber or pit in which combustion occurs. Incinerators of this type can be constructed above or below ground and with or without refractory walls and floor. (Air curtain incinerators are not to be confused with conventional combustion devices with enclosed fireboxes and controlled air technology such as mass burn, modular, and fluidized bed combustors.)

Annual heat input means the heat input for the 12 months preceding the compliance demonstration.

Auxiliary fuel means natural gas, liquified petroleum gas, fuel oil, or diesel fuel.

Average annual heat input rate means annual heat input divided by the hours of operation for the 12 months preceding the compliance demonstration.

Bag leak detection system means an instrument that is capable of monitoring particulate matter loadings in the exhaust of a fabric filter (*i.e.,* baghouse) in order to detect bag failures. A bag leak detection system includes, but is not limited to, an instrument that operates on triboelectric, light scattering, light transmittance, or other principle to monitor relative particulate matter loadings.

Burn-off oven means any rack reclamation unit, part reclamation unit, or drum reclamation unit. A burn-off oven is not an incinerator, waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Bypass stack means a device used for discharging combustion gases to avoid severe damage to the air pollution control device or other equipment.

Calendar quarter means three consecutive months (nonoverlapping) beginning on: January 1, April 1, July 1, or October 1.

Calendar year means 365 consecutive days starting on January 1 and ending on December 31.

CEMS data during startup and shutdown means the following:

(1) For incinerators and small remote incinerators: CEMS data collected during the first hours of a CISWI unit startup from a cold start until waste is fed to the unit and the hours of operation following the cessation of waste material being fed to the CISWI unit during a unit shutdown. For each startup event, the length of time that CEMS data may be claimed as being CEMS data during startup must be 48 operating hours or less. For each shutdown event, the length of time that CEMS data may be claimed as being CEMS data during shutdown must be 24 operating hours or less;

(2) For energy recovery units: CEMS data collected during the startup or shutdown periods of operation. Startup begins with either the first-ever firing of fuel in a boiler or process heater for the purpose of supplying useful thermal energy (such as steam or heat) for heating, cooling or process purposes, or producing electricity, or the firing of fuel in a boiler or process heater for any purpose after a shutdown event. Startup ends four hours after when the boiler or process heater makes useful thermal energy (such as heat or steam) for heating, cooling, or process purposes, or generates electricity, whichever is earlier. Shutdown begins when the boiler or process heater no longer makes useful thermal energy (such as heat or steam) for heating, cooling, or process purposes and/or generates electricity or when no fuel is being fed to the boiler or process heater, whichever is earlier. Shutdown ends when the boiler or process heater no longer makes useful thermal energy (such as steam or heat) for heating, cooling, or process purposes and/or generates electricity, and no fuel is being combusted in the boiler or process heater; and

(3) For waste-burning kilns: CEMS data collected during the periods of kiln operation that do not include normal operations. Startup means the time from when a shutdown kiln first begins firing fuel until it begins producing clinker. Startup begins when a shutdown kiln turns on the induced draft fan and begins firing fuel in the main burner. Startup ends when feed is being continuously introduced into the kiln for at least 120 minutes or when the feed rate exceeds 60 percent of the kiln design limitation rate, whichever occurs first. Shutdown means the cessation of kiln operation. Shutdown begins when feed to the kiln is halted and ends when continuous kiln rotation ceases.

Chemical recovery unit means combustion units burning materials to recover chemical constituents or to produce chemical compounds where there is an existing commercial market for such recovered chemical constituents or compounds. A chemical recovery unit is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart. The following seven types of units are considered chemical recovery units:

(1) Units burning only pulping liquors (*i.e.*, black liquor) that are reclaimed in a pulping liquor recovery process and reused in the pulping process;

(2) Units burning only spent sulfuric acid used to produce virgin sulfuric acid;

(3) Units burning only wood or coal feedstock for the production of charcoal;

(4) Units burning only manufacturing byproduct streams/residue containing catalyst metals that are reclaimed and reused as catalysts or used to produce commercial grade catalysts;

(5) Units burning only coke to produce purified carbon monoxide that is used as an intermediate in the production of other chemical compounds;

(6) Units burning only hydrocarbon liquids or solids to produce hydrogen, carbon monoxide, synthesis gas, or other gases for use in other manufacturing processes; and

(7) Units burning only photographic film to recover silver.

Chemotherapeutic waste means waste material resulting from the production or use of antineoplastic agents used for the purpose of stopping or reversing the growth of malignant cells.

Clean lumber means wood or wood products that have been cut or shaped and include wet, air-dried, and kiln-dried wood products. Clean lumber does not include wood products that have been painted, pigment-stained, or pressure-treated by compounds such as chromate copper arsenate, pentachlorophenol, and creosote.

Commercial and industrial solid waste incineration (CISWI) unit means any distinct operating unit of any commercial or industrial facility that combusts, or has combusted in the preceding 6 months, any solid waste as that term is defined in 40 CFR part 241. If the operating unit burns materials other than traditional fuels as defined in § 241.2 that have been discarded, and you do not keep and produce records as required by § 60.2175(v), the operating unit is a CISWI unit. While not all CISWI units will include all of the following components, a CISWI unit includes, but is not limited to, the solid waste feed system, grate system, flue gas system, waste heat recovery equipment, if any, and bottom ash system. The CISWI unit does not include air pollution control equipment or the stack. The CISWI unit boundary starts at the solid waste hopper (if applicable) and extends through two areas: The combustion unit flue gas system, which ends immediately after the last combustion chamber or after the waste heat recovery equipment, if any; and the combustion unit bottom ash system, which ends at the truck loading station or similar equipment that transfers the ash to final disposal. The CISWI unit includes all ash handling systems connected to the bottom ash handling system.

Contained gaseous material means gases that are in a container when that container is combusted.

Continuous emission monitoring system (CEMS) means the total equipment that may be required to meet the data acquisition and availability requirements of this subpart, used to sample, condition (if applicable), analyze, and provide a record of emissions.

Continuous monitoring system (CMS) means the total equipment, required under the emission monitoring sections in applicable subparts, used to sample and condition (if applicable), to analyze, and to provide a permanent record of emissions or process parameters. A particulate matter continuous parameter monitoring system (PM CPMS) is a type of CMS.

Cyclonic burn barrel means a combustion device for waste materials that is attached to a 55 gallon, open-head drum. The device consists of a lid, which fits onto and encloses the drum, and a blower that forces combustion air into the drum in a cyclonic manner to enhance the mixing of waste material and air. A cyclonic burn barrel is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Deviation means any instance in which an affected source subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart, including but not limited to any emission limitation, operating limit, or operator qualification and accessibility requirements; and

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any affected source required to obtain such a permit.

Dioxins/furans means tetra- through octa-chlorinated dibenzo-p-dioxins and dibenzofurans.

Discard means, for purposes of this subpart and 40 CFR part 60, subpart DDDD, only, burned in an incineration unit without energy recovery.

Drum reclamation unit means a unit that burns residues out of drums (*e.g.,* 55 gallon drums) so that the drums can be reused.

Dry scrubber means an add-on air pollution control system that injects dry alkaline sorbent (dry injection) or sprays an alkaline sorbent (spray dryer) to react with and neutralize acid gas in the exhaust stream forming a dry powder material. Sorbent injection systems in fluidized bed boilers and process heaters are included in this definition. A dry scrubber is a dry control system.

Energy recovery means the process of recovering thermal energy from combustion for useful purposes such as steam generation or process heating.

Energy recovery unit means a combustion unit combusting solid waste (as that term is defined by the Administrator in 40 CFR part 241) for energy recovery. Energy recovery units include units that would be considered boilers and process heaters if they did not combust solid waste.

Energy recovery unit designed to burn biomass (Biomass) means an energy recovery unit that burns solid waste, biomass, and non-coal solid materials but less than 10 percent coal, on a heat input basis on an annual average, either alone or in combination with liquid waste, liquid fuel or gaseous fuels.

Energy recovery unit designed to burn coal (Coal) means an energy recovery unit that burns solid waste and at least 10 percent coal on a heat input basis on an annual average, either alone or in combination with liquid waste, liquid fuel or gaseous fuels.

Energy recovery unit designed to burn liquid waste materials and gas (Liquid/gas) means an energy recovery unit that burns a liquid waste with liquid or gaseous fuels not combined with any solid fuel or waste materials.

Energy recovery unit designed to burn solid materials (Solids) includes energy recovery units designed to burn coal and energy recovery units designed to burn biomass.

Fabric filter means an add-on air pollution control device used to capture particulate matter by filtering gas streams through filter media, also known as a baghouse.

Foundry sand thermal reclamation unit means a type of part reclamation unit that removes coatings that are on foundry sand. A foundry sand thermal reclamation unit is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Incinerator means any furnace used in the process of combusting solid waste (as that term is defined by the Administrator in 40 CFR part 241) for the purpose of reducing the volume of the waste by removing combustible matter. Incinerator designs include single chamber and two-chamber.

In-line coal mill means those coal mills using kiln exhaust gases in their process. Coal mills with a heat source other than the kiln or coal mills using exhaust gases from the clinker cooler alone are not an in-line coal mill.

In-line kiln/raw mill means a system in a Portland Cement production process where a dry kiln system is integrated with the raw mill so that all or a portion of the kiln exhaust gases are used to perform the drying operation of the raw mill, with no auxiliary heat source used. In this system the kiln is capable of operating without the raw mill operating, but the raw mill cannot operate without the kiln gases, and consequently, the raw mill does not generate a separate exhaust gas stream.

Kiln means an oven or furnace, including any associated preheater or precalciner devices, in-line raw mills, in-line coal mills or alkali bypasses used for processing a substance by burning, firing or drying. Kilns include cement kilns that produce clinker by heating limestone and other materials for subsequent production of Portland Cement. Because the alkali bypass, in-line raw mill and in-line coal mill are considered an integral part of the kiln, the kiln emissions limits also apply to the exhaust of the alkali bypass, in-line raw mill and in-line coal mill.

Laboratory analysis unit means units that burn samples of materials for the purpose of chemical or physical analysis. A laboratory analysis unit is not an incinerator, waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Load fraction means the actual heat input of an energy recovery unit divided by heat input during the performance test that established the minimum sorbent injection rate or minimum activated carbon injection rate, expressed as a fraction (*e.g.,* for 50 percent load the load fraction is 0.5).

Low-level radioactive waste means waste material which contains radioactive nuclides emitting primarily beta or gamma radiation, or both, in concentrations or quantities that exceed applicable federal or state standards for unrestricted release. Low-level radioactive waste is not high-level radioactive waste, spent nuclear fuel, or byproduct material as defined by the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)(2)).

Malfunction means any sudden, infrequent, and not reasonably preventable failure of air pollution control equipment, process equipment, or a process to operate in a normal or usual manner. Failures that are caused, in part, by poor maintenance or careless operation are not malfunctions.

Minimum voltage or amperage means 90 percent of the lowest test-run average voltage or amperage to the electrostatic precipitator measured during the most recent particulate matter or mercury performance test demonstrating compliance with the applicable emission limits.

Modification or *modified CISWI unit* means a CISWI unit that has been changed later than August 7, 2013 and that meets one of two criteria:

(1) The cumulative cost of the changes over the life of the unit exceeds 50 percent of the original cost of building and installing the CISWI unit (not including the cost of land) updated to current costs (current dollars). To determine what systems are within the boundary of the CISWI unit used to calculate these costs, see the definition of CISWI unit; and

(2) Any physical change in the CISWI unit or change in the method of operating it that increases the amount of any air pollutant emitted for which section 129 or section 111 of the Clean Air Act has established standards.

Municipal solid waste or municipal-type solid waste means household, commercial/retail, or institutional waste. Household waste includes material discarded by residential dwellings, hotels, motels, and other similar permanent or temporary housing. Commercial/retail waste includes material discarded by stores, offices, restaurants, warehouses, nonmanufacturing activities at industrial facilities, and other similar establishments or facilities. Institutional waste includes materials discarded by schools, by hospitals (nonmedical), by nonmanufacturing activities at prisons and government facilities, and other similar establishments or facilities. Household, commercial/retail, and institutional waste does include yard waste and refuse-derived fuel. Household, commercial/retail, and institutional waste does not include used oil; sewage sludge; wood pallets; construction, renovation, and demolition wastes (which include railroad ties and telephone poles); clean wood; industrial process or manufacturing wastes; medical waste; or motor vehicles (including motor vehicle parts or vehicle fluff).

Opacity means the degree to which emissions reduce the transmission of light and obscure the view of an object in the background.

Operating day means a 24-hour period between 12 midnight and the following midnight during which any amount of solid waste is combusted at any time in the CISWI unit.

Oxygen analyzer system means all equipment required to determine the oxygen content of a gas stream and used to monitor oxygen in the boiler or process heater flue gas, boiler or process heater, firebox, or other appropriate location. This definition includes oxygen trim systems and certified oxygen CEMS. The source owner or operator is responsible to install, calibrate, maintain, and operate the oxygen analyzer system in accordance with the manufacturer's recommendations.

Oxygen trim system means a system of monitors that is used to maintain excess air at the desired level in a combustion device over its operating range. A typical system consists of a flue gas oxygen and/or carbon monoxide monitor that automatically provides a feedback signal to the combustion air controller or draft controller.

Part reclamation unit means a unit that burns coatings off parts (*e.g.*, tools, equipment) so that the parts can be reconditioned and reused.

Particulate matter means total particulate matter emitted from CISWI units as measured by Method 5 or Method 29 of appendix A of this part.

Pathological waste means waste material consisting of only human or animal remains, anatomical parts, and/or tissue, the bags/containers used to collect and transport the waste material, and animal bedding (if applicable).

Performance evaluation means the conduct of relative accuracy testing, calibration error testing, and other measurements used in validating the continuous monitoring system data.

Performance test means the collection of data resulting from the execution of a test method (usually three emission test runs) used to demonstrate compliance with a relevant emission standard as specified in the performance test section of the relevant standard.

Process change means any of the following physical or operational changes:

(1) A physical change (maintenance activities excluded) to the CISWI unit which may increase the emission rate of any air pollutant to which a standard applies;

(2) An operational change to the CISWI unit where a new type of non-hazardous secondary material is being combusted;

(3) A physical change (maintenance activities excluded) to the air pollution control devices used to comply with the emission limits for the CISWI unit (*e.g.*, replacing an electrostatic precipitator with a fabric filter); and

(4) An operational change to the air pollution control devices used to comply with the emission limits for the affected CISWI unit (*e.g.*, change in the sorbent injection rate used for activated carbon injection).

Rack reclamation unit means a unit that burns the coatings off racks used to hold small items for application of a coating. The unit burns the coating overspray off the rack so the rack can be reused.

Raw mill means a ball or tube mill, vertical roller mill or other size reduction equipment, that is not part of an in-line kiln/raw mill, used to grind feed to the appropriate size. Moisture may be added or removed from the feed during the grinding operation. If the raw mill is used to remove moisture from feed materials, it is also, by definition, a raw material dryer. The raw mill also includes the air separator associated with the raw mill.

Reconstruction means rebuilding a CISWI unit and meeting two criteria:

(1) The reconstruction begins on or after August 7, 2013; and

(2) The cumulative cost of the construction over the life of the incineration unit exceeds 50 percent of the original cost of building and installing the CISWI unit (not including land) updated to current costs (current dollars). To determine what systems are within the boundary of the CISWI unit used to calculate these costs, see the definition of CISWI unit.

Refuse-derived fuel means a type of municipal solid waste produced by processing municipal solid waste through shredding and size classification. This includes all classes of refuse-derived fuel including two fuels:

(1) Low-density fluff refuse-derived fuel through densified refuse-derived fuel; and

(2) Pelletized refuse-derived fuel.

Responsible official means one of the following:

(1) For a corporation: A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation, or a duly authorized representative of such person if the representative is responsible for the overall operation of one or more manufacturing, production, or operating facilities applying for or subject to a permit and either:

(i) The facilities employ more than 250 persons or have gross annual sales or expenditures exceeding $25 million (in second quarter 1980 dollars); or

(ii) The delegation of authority to such representatives is approved in advance by the permitting authority;

(2) For a partnership or sole proprietorship: A general partner or the proprietor, respectively;

(3) For a municipality, state, federal, or other public agency: Either a principal executive officer or ranking elected official. For the purposes of this part, a principal executive officer of a federal agency includes the chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency (*e.g.*, a Regional Administrator of EPA); or

(4) For affected facilities:

(i) The designated representative in so far as actions, standards, requirements, or prohibitions under Title IV of the Clean Air Act or the regulations promulgated thereunder are concerned; or

(ii) The designated representative for any other purposes under part 60.

Shutdown means, for incinerators and small, remote incinerators, the period of time after all waste has been combusted in the primary chamber.

Small, remote incinerator means an incinerator that combusts solid waste (as that term is defined by the Administrator in 40 CFR part 241) and combusts 3 tons per day or less solid waste and is more than 25 miles driving distance to the nearest municipal solid waste landfill.

Soil treatment unit means a unit that thermally treats petroleum-contaminated soils for the sole purpose of site remediation. A soil treatment unit may be direct-fired or indirect fired. A soil treatment unit is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Solid waste means the term solid waste as defined in 40 CFR 241.2.

Solid waste incineration unit means a distinct operating unit of any facility which combusts any solid waste (as that term is defined by the Administrator in 40 CFR part 241) material from commercial or industrial establishments or the general public (including single and multiple residences, hotels and motels). Such term does not include incinerators or other units required to have a permit under section 3005 of the Solid Waste Disposal Act. The term "solid waste incineration unit" does not include:

(1) Materials recovery facilities (including primary or secondary smelters) which combust waste for the primary purpose of recovering metals;

(2) Qualifying small power production facilities, as defined in section 3(17)(C) of the Federal Power Act (16 U.S.C. 769(17)(C)), or qualifying cogeneration facilities, as defined in section 3(18)(B) of the Federal Power Act (16 U.S.C. 796(18)(B)), which burn homogeneous waste (such as units which burn tires or used oil, but not including refuse-derived fuel) for the production of electric energy or in the case of qualifying cogeneration facilities which burn homogeneous waste for the production of electric energy and steam or forms of useful energy (such as heat) which are used for industrial, commercial, heating or cooling purposes; or

(3) Air curtain incinerators provided that such incinerators only burn wood wastes, yard wastes, and clean lumber and that such air curtain incinerators comply with opacity limitations to be established by the Administrator by rule.

Space heater means a unit that meets the requirements of 40 CFR 279.23. A space heater is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Standard conditions, when referring to units of measure, means a temperature of 68 °F (20 °C) and a pressure of 1 atmosphere (101.3 kilopascals).

Startup period means, for incinerators and small, remote incinerators, the period of time between the activation of the system and the first charge to the unit.

Useful thermal energy means energy (*i.e.,* steam, hot water, or process heat) that meets the minimum operating temperature and/or pressure required by any energy use system that uses energy provided by the affected energy recovery unit.

Waste-burning kiln means a kiln that is heated, in whole or in part, by combusting solid waste (as that term is defined by the Administrator in 40 CFR part 241). Secondary materials used in Portland cement kilns shall not be deemed to be combusted unless they are introduced into the flame zone in the hot end of the kiln or mixed with the precalciner fuel.

Wet scrubber means an add-on air pollution control device that uses an aqueous or alkaline scrubbing liquor to collect particulate matter (including nonvaporous metals and condensed organics) and/or to absorb and neutralize acid gases.

Wood waste means untreated wood and untreated wood products, including tree stumps (whole or chipped), trees, tree limbs (whole or chipped), bark, sawdust, chips, scraps, slabs, millings, and shavings. Wood waste does not include:

(1) Grass, grass clippings, bushes, shrubs, and clippings from bushes and shrubs from residential, commercial/retail, institutional, or industrial sources as part of maintaining yards or other private or public lands;

(2) Construction, renovation, or demolition wastes; and

(3) Clean lumber.

Table 1 to Subpart CCCC of Part 60—Emission Limitations for Incinerators for Which Construction Is Commenced After November 30, 1999, But No Later Than June 4, 2010, or for Which Modification or Reconstruction Is Commenced on or After June 1, 2001, But No Later Than August 7, 2013

For the air pollutant	You must meet this emission limitation [1]	Using this averaging time	And determining compliance using this method
Cadmium	0.004 milligrams per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Performance test (Method 29 of appendix A of this part).
Carbon monoxide	157 parts per million by dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 10 at 40 CFR part 60, appendix A–4).
Dioxin/Furan (toxic equivalency basis).	0.41 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meters per run).	Performance test (Method 23 of appendix A–7 of this part).
Hydrogen chloride	62 parts per million by dry volume.	3-run average (For Method 26, collect a minimum volume of 120 liters per run. For Method 26A, collect a minimum volume of 1 dry standard cubic meter per run).	Performance test (Method 26 or 26A at 40 CFR part 60, appendix A–8).
Lead	0.04 milligrams per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Performance test (Method 29 of appendix A of this part).
Mercury	0.47 milligrams per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Performance test (Method 29 of appendix A of this part).
Nitrogen Oxides	388 parts per million by dry volume.	3-run average (for Method 7E, 1 hour minimum sample time per run).	Performance test (Method 7 or 7E at 40 CFR part 60, appendix A–4).
Opacity	10 percent	6-minute averages	Performance test (Method 9 of appendix A of this part).
Oxides of nitrogen	388 parts per million by dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 7, 7A, 7C, 7D, or 7E of appendix A of this part).
Particulate matter	70 milligrams per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Performance test (Method 5 or 29 of appendix A of this part).

TABLE 1 TO SUBPART CCCC OF PART 60—EMISSION LIMITATIONS FOR INCINERATORS FOR WHICH CONSTRUCTION IS COMMENCED AFTER NOVEMBER 30, 1999, BUT NO LATER THAN JUNE 4, 2010, OR FOR WHICH MODIFICATION OR RECONSTRUCTION IS COMMENCED ON OR AFTER JUNE 1, 2001, BUT NO LATER THAN AUGUST 7, 2013—Continued

For the air pollutant	You must meet this emission limitation[1]	Using this averaging time	And determining compliance using this method
Sulfur Dioxide	20 parts per million by dry volume.	3-run average (For Method 6, collect a minimum volume of 20 liters per run. For Method 6C, collect sample for a minimum duration of 1 hour per run).	Performance test (Method 6 or 6C at 40 CFR part 60, appendix A–4).

[1] All emission limitations (except for opacity) are measured at 7 percent oxygen, dry basis at standard conditions.

TABLE 2 TO SUBPART CCCC OF PART 60—OPERATING LIMITS FOR WET SCRUBBERS

For these operating parameters	You must establish these operating limits	And monitoring using these minimum frequencies		
		Data measurement	Data recording	Averaging time
Charge rate	Maximum charge rate	Continuous	Every hour	Daily (batch units) 3-hour rolling (continuous and intermittent units).[1]
Pressure drop across the wet scrubber or amperage to wet scrubber.	Minimum pressure drop or amperage.	Continuous	Every 15 minutes.	3-hour rolling.[1]
Scrubber liquor flow rate	Minimum flow rate	Continuous	Every 15 minutes.	3-hour rolling.[1]
Scrubber liquor pH	Minimum pH	Continuous	Every 15 minutes.	3-hour rolling.[1]

[1] Calculated each hour as the average of the previous 3 operating hours.

TABLE 3 TO SUBPART CCCC OF PART 60—TOXIC EQUIVALENCY FACTORS

Dioxin/furan congener	Toxic equivalency factor
2,3,7,8-tetrachlorinated dibenzo-p-dioxin	1
1,2,3,7,8-pentachlorinated dibenzo-p-dioxin	0.5
1,2,3,4,7,8-hexachlorinated dibenzo-p-dioxin	0.1
1,2,3,7,8,9-hexachlorinated dibenzo-p-dioxin	0.1
1,2,3,6,7,8-hexachlorinated dibenzo-p-dioxin	0.1
1,2,3,4,6,7,8-heptachlorinated dibenzo-p-dioxin	0.01
Octachlorinated dibenzo-p-dioxin	0.001
2,3,7,8-tetrachlorinated dibenzofuran	0.1
2,3,4,7,8-pentachlorinated dibenzofuran	0.5
1,2,3,7,8-pentachlorinated dibenzofuran	0.05
1,2,3,4,7,8-hexachlorinated dibenzofuran	0.1
1,2,3,6,7,8-hexachlorinated dibenzofuran	0.1
1,2,3,7,8,9-hexachlorinated dibenzofuran	0.1
2,3,4,6,7,8-hexachlorinated dibenzofuran	0.1
1,2,3,4,6,7,8-heptachlorinated dibenzofuran	0.01
1,2,3,4,7,8,9-heptachlorinated dibenzofuran	0.01
Octachlorinated dibenzofuran	0.001

TABLE 4 TO SUBPART CCCC OF PART 60—SUMMARY OF REPORTING REQUIREMENTS[1]

Report	Due date	Contents	Reference
Preconstruction report	Prior to commencing construction.	Statement of intent to construct Anticipated date of commencement of construction. Documentation for siting requirements. Waste management plan. Anticipated date of initial startup.	§ 60.2190.
Startup notification	Prior to initial startup	• Type of waste to be burned • Maximum design waste burning capacity. • Anticipated maximum charge rate. • If applicable, the petition for site-specific operating limits.	§ 60.2195.

TABLE 4 TO SUBPART CCCC OF PART 60—SUMMARY OF REPORTING REQUIREMENTS [1]—Continued

Report	Due date	Contents	Reference
Initial test report	No later than 60 days following the initial performance test.	• Complete test report for the initial performance test. • The values for the site-specific operating limits. • Installation of bag leak detection system for fabric filter.	§ 60.2200.
Annual report	No later than 12 months following the submission of the initial test report. Subsequent reports are to be submitted no more than 12 months following the previous report.	• Name and address • Statement and signature by responsible official. • Date of report. • Values for the operating limits. • Highest recorded 3-hour average and the lowest 3-hour average, as applicable, for each operating parameter recorded for the calendar year being reported. • For each performance test conducted during the reporting period, if any performance test is conducted, the process unit(s) tested, the pollutant(s) tested, and the date that such performance test was conducted. • If a performance test was not conducted during the reporting period, a statement that the requirements of § 60.2155(a) were met. • Documentation of periods when all qualified CISWI unit operators were unavailable for more than 8 hours but less than 2 weeks. • If you are conducting performance tests once every 3 years consistent with § 60.2155(a), the date of the last 2 performance tests, a comparison of the emission level you achieved in the last 2 performance tests to the 75 percent emission limit threshold required in § 60.2155(a) and a statement as to whether there have been any operational changes since the last performance test that could increase emissions.	§§ 60.2205 and 60.2210.
Emission limitation or operating limit deviation report.	By August 1 of that year for data collected during the first half of the calendar year. By February 1 of the following year for data collected during the second half of the calendar year.	• Dates and times of deviation • Averaged and recorded data for those dates. • Duration and causes of each deviation and the corrective actions taken. • Copy of operating limit monitoring data and, if any performance test was conducted that documents emission levels, the process unit(s) tested, the pollutant(s) tested, and the date that such performance text was conducted. • Dates, times and causes for monitor downtime incidents.	§ 60.2215 and 60.2220.
Qualified operator deviation notification.	Within 10 days of deviation	• Statement of cause of deviation • Description of efforts to have an accessible qualified operator. • The date a qualified operator will be accessible.	§ 60.2225(a)(1).
Qualified operator deviation status report.	Every 4 weeks following deviation.	• Description of efforts to have an accessible qualified operator. • The date a qualified operator will be accessible. • Request for approval to continue operation.	§ 60.2225(a)(2).
Qualified operator deviation notification of resumed operation.	Prior to resuming operation	• Notification that you are resuming operation.	§ 60.2225(b).

[1] This table is only a summary, see the referenced sections of the rule for the complete requirements.

TABLE 5 TO SUBPART CCCC OF PART 60—EMISSION LIMITATIONS FOR INCINERATORS THAT COMMENCED CONSTRUCTION AFTER JUNE 4, 2010, OR THAT COMMENCED RECONSTRUCTION OR MODIFICATION AFTER AUGUST 7, 2013

For the air pollutant	You must meet this emission limitation[1]	Using this averaging time	And determining compliance using this method
Cadmium	0.0023 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meter per run).	Performance test (Method 29 at 40 CFR part 60, appendix A–8 of this part). Use ICPMS for the analytical finish.
Carbon monoxide	17 parts per million by dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 10 at 40 CFR part 60, appendix A–4).
Dioxin/furan (Total Mass Basis).	0.58 nanograms per dry standard cubic meter[3].	3-run average (collect a minimum volume of 4 dry standard cubic meters per run).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Dioxin/furan (toxic equivalency basis).	0.13 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meter per run).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Fugitive ash	Visible emissions for no more than 5 percent of the hourly observation period.	Three 1-hour observation periods	Visible emission test (Method 22 at 40 CFR part 60, appendix A–7).
Hydrogen chloride	0.091 parts per million by dry volume.	3-run average (For Method 26, collect a minimum volume of 360 liters per run. For Method 26A, collect a minimum volume of 3 dry standard cubic meters per run).	Performance test (Method 26 or 26A at 40 CFR part 60, appendix A–8).
Lead	0.015 milligrams per dry standard cubic meter[3].	3-run average (collect a minimum volume of 4 dry standard cubic meters per run).	Performance test (Method 29 of appendix A–8 at 40 CFR part 60). Use ICPMS for the analytical finish.
Mercury	0.00084 milligrams per dry standard cubic meter[3].	3-run average (collect enough volume to meet a detection limit data quality objective of 0.03 ug/dry standard cubic meter).	Performance test (Method 29 or 30B at 40 CFR part 60, appendix A–8) or ASTM D6784–02 (Reapproved 2008).[2]
Nitrogen Oxides	23 parts per million dry volume.	3-run average (for Method 7E, 1 hour minimum sample time per run).	Performance test (Method 7 or 7E at 40 CFR part 60, appendix A–4).
Particulate matter (filterable)	18 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 2 dry standard cubic meters per run).	Performance test (Method 5 or 29 at 40 CFR part 60, appendix A–3 or appendix A–8 at 40 CFR part 60).
Sulfur dioxide	11 parts per million dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 6 or 6C at 40 CFR part 60, appendix A–4).

[1] All emission limitations are measured at 7 percent oxygen, dry basis at standard conditions. For dioxins/furans, you must meet either the Total Mass Limit or the toxic equivalency basis limit.

[2] Incorporated by reference, *see* § 60.17.

[3] If you are conducting stack tests to demonstrate compliance and your performance tests for this pollutant for at least 2 consecutive years show that your emissions are at or below this limit, you can skip testing according to § 60.2155 if all of the other provisions of § 60.2155 are met. For all other pollutants that do not contain a footnote "3", your performance tests for this pollutant for at least 2 consecutive years must show that your emissions are at or below 75 percent of this limit in order to qualify for skip testing.

TABLE 6 TO SUBPART CCCC OF PART 60—EMISSION LIMITATIONS FOR ENERGY RECOVERY UNITS THAT COMMENCED CONSTRUCTION AFTER JUNE 4, 2010, OR THAT COMMENCED RECONSTRUCTION OR MODIFICATION AFTER AUGUST 7, 2013

For the air pollutant	You must meet this emission limitation[1]		Using this averaging time	And determining compliance using this method
	Liquid/gas	Solids		
Cadmium	0.023 milligrams per dry standard cubic meter.	Biomass—0.0014 milligrams per dry standard cubic meter.[3] Coal—0.0017 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meters per run).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Carbon monoxide	35 parts per million dry volume.	Biomass—240 parts per million dry volume. Coal—95 parts per million dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 10 at 40 CFR part 60, appendix A–4).
Dioxin/furans (Total Mass Basis).	No Total Mass Basis limit, must meet the toxic equivalency basis limit below.	Biomass—0.52 nanograms per dry standard cubic meter.[3] Coal—5.1 nanograms per dry standard cubic meter[3].	3-run average (collect a minimum volume of 4 dry standard cubic meters).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Dioxins/furans (toxic equivalency basis).	0.093 nanograms per dry standard cubic meter[3].	Biomass—0.076 nanograms per dry standard cubic meter.[3] Coal—0.075 nanograms per dry standard cubic meter[3].	3-run average (collect a minimum volume of 4 dry standard cubic meters per run).	Performance test (Method 23 of appendix A–7 of this part).

TABLE 6 TO SUBPART CCCC OF PART 60—EMISSION LIMITATIONS FOR ENERGY RECOVERY UNITS THAT COMMENCED CONSTRUCTION AFTER JUNE 4, 2010, OR THAT COMMENCED RECONSTRUCTION OR MODIFICATION AFTER AUGUST 7, 2013—Continued

For the air pollutant	You must meet this emission limitation[1]		Using this averaging time	And determining compliance using this method
	Liquid/gas	Solids		
Fugitive ash	Visible emissions for no more than 5 percent of the hourly observation period.	Three 1-hour observation periods	Visible emission test (Method 22 at 40 CFR part 60, appendix A–7).	Fugitive ash.
Hydrogen chloride	14 parts per million dry volume.	Biomass—0.20 parts per million dry volume. Coal—58 parts per million dry volume.	3-run average (For Method 26, collect a minimum volume of 360 liters per run. For Method 26A, collect a minimum volume of 3 dry standard cubic meters per run).	Performance test (Method 26 or 26A at 40 CFR part 60, appendix A–8).
Lead	0.096 milligrams per dry standard cubic meter.	Biomass—0.014 milligrams per dry standard cubic meter.[3] Coal—0.057 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meters per run).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Mercury	0.00056 milligrams per dry standard cubic meter[3].	Biomass—0.0022 milligrams per dry standard cubic meter. Coal—0.013 milligrams per dry standard cubic meter.	3-run average (collect enough volume to meet an in-stack detection limit data quality objective of 0.03 ug/dscm).	Performance test (Method 29 or 30B at 40 CFR part 60, appendix A–8) or ASTM D6784–02 (Reapproved 2008).[2]
Oxides of nitrogen	76 parts per million dry volume.	Biomass—290 parts per million dry volume. Coal—460 parts per million dry volume.	3-run average (for Method 7E, 1 hour minimum sample time per run).	Performance test (Method 7 or 7E at 40 CFR part 60, appendix A–4).
Particulate matter (filterable).	110 milligrams per dry standard cubic meter.	Biomass—5.1 milligrams per dry standard cubic meter. Coal—130 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meter per run).	Performance test (Method 5 or 29 at 40 CFR part 60, appendix A–3 or appendix A–8) if the unit has an annual average heat input rate less than 250 MMBtu/hr; or PM CPMS (as specified in § 60.2145(x)) if the unit has an annual average heat input rate equal to or greater than 250 MMBtu/hr.
Sulfur dioxide	720 parts per million dry volume.	Biomass—7.3 parts per million dry volume. Coal—850 parts per million dry volume.	3-run average (for Method 6, collect a minimum of 60 liters, for Method 6C, 1 hour minimum sample time per run).	Performance test (Method 6 or 6C at 40 CFR part 60, appendix A–4).

[1] All emission limitations are measured at 7 percent oxygen, dry basis at standard conditions. For dioxins/furans, you must meet either the Total Mass Basis limit or the toxic equivalency basis limit.

[2] Incorporated by reference, *see* § 60.17.

[3] If you are conducting stack tests to demonstrate compliance and your performance tests for this pollutant for at least 2 consecutive years show that your emissions are at or below this limit, you can skip testing according to § 60.2155 if all of the other provisions of § 60.2155 are met. For all other pollutants that do not contain a footnote "3", your performance tests for this pollutant for at least 2 consecutive years must show that your emissions are at or below 75 percent of this limit in order to qualify for skip testing.

TABLE 7 TO SUBPART CCCC OF PART 60—EMISSION LIMITATIONS FOR WASTE-BURNING KILNS THAT COMMENCED CONSTRUCTION AFTER JUNE 4, 2010, OR RECONSTRUCTION OR MODIFICATION AFTER AUGUST 7, 2013

For the air pollutant	You must meet this emission limitation[1]	Using this averaging time	And determining compliance using this method[3]
Cadmium	0.0014 milligrams per dry standard cubic meter[2].	3-run average (collect a minimum volume of 4 dry standard cubic meters per run).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Carbon monoxide	90 (long kilns)/190 (preheater/precalciner) parts per million dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 10 at 40 CFR part 60, appendix A–4).
Dioxins/furans (total mass basis).	0.51 nanograms per dry standard cubic meter[2].	3-run average (collect a minimum volume of 4 dry standard cubic meters per run).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Dioxins/furans (toxic equivalency basis).	0.075 nanograms per dry standard cubic meter[2].	3-run average (collect a minimum volume of 4 dry standard cubic meters).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).

TABLE 7 TO SUBPART CCCC OF PART 60—EMISSION LIMITATIONS FOR WASTE-BURNING KILNS THAT COMMENCED CONSTRUCTION AFTER JUNE 4, 2010, OR RECONSTRUCTION OR MODIFICATION AFTER AUGUST 7, 2013—Continued

For the air pollutant	You must meet this emission limitation [1]	Using this averaging time	And determining compliance using this method [3]
Hydrogen chloride	3.0 parts per million dry volume [2].	3-run average (1 hour minimum sample time per run) or 30-day rolling average if HCl CEMS are used.	Performance test (Method 321 at 40 CFR part 63, appendix A) or HCl CEMS if a wet scrubber or dry scrubber is not used, as specified in § 60.2145(j).
Lead	0.014 milligrams per dry standard cubic meter [2].	3-run average (collect a minimum volume of 4 dry standard cubic meters).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Mercury	0.0037 milligrams per dry standard cubic meter.	30-day rolling average	Mercury CEMS or sorbent trap monitoring system (performance specification 12A or 12B, respectively, of appendix B of this part), as specified in § 60.2145(j).
Oxides of nitrogen	200 parts per million dry volume.	30-day rolling average	NO_X CEMS (performance specification 2 of appendix B and procedure 1 of appendix F of this part).
Particulate matter (filterable).	4.9 milligrams per dry standard cubic meter.	30-day rolling average	PM CPMS (as specified in § 60.2145(x)).
Sulfur dioxide	28 parts per million dry volume.	30-day rolling average	Sulfur dioxide CEMS (performance specification 2 of appendix B and procedure 1 of appendix F of this part).

[1] All emission limitations are measured at 7 percent oxygen (except for CEMS data during startup and shutdown), dry basis at standard conditions. For dioxins/furans, you must meet either the Total Mass Basis limit or the toxic equivalency basis limit.

[2] If you are conducting stack tests to demonstrate compliance and your performance tests for this pollutant for at least 2 consecutive years show that your emissions are at or below this limit, you can skip testing according to § 60.2155 if all of the other provisions of § 60.2155 are met. For all other pollutants that do not contain a footnote "2", your performance tests for this pollutant for at least 2 consecutive years must show that your emissions are at or below 75 percent of this limit in order to qualify for skip testing.

[3] Alkali bypass and in-line coal mill stacks are subject to performance testing only, as specified in § 60.2145(y)(3). They are not subject to the CEMS, sorbent trap or CPMS requirements that otherwise may apply to the main kiln exhaust.

TABLE 8 TO SUBPART CCCC OF PART 60—EMISSION LIMITATIONS FOR SMALL, REMOTE INCINERATORS THAT COMMENCED CONSTRUCTION AFTER JUNE 4, 2010, OR THAT COMMENCED RECONSTRUCTION OR MODIFICATION AFTER AUGUST 7, 2013

For the air pollutant	You must meet this emission limitation [1]	Using this averaging time	And determining compliance using this method
Cadmium	0.67 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters per run).	Performance test (Method 29 at 40 CFR part 60, appendix A–8).
Carbon monoxide	13 parts per million dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 10 at 40 CFR part 60, appendix A–4).
Dioxins/furans (total mass basis).	1,800 nanograms per dry standard cubic meter..	3-run average (collect a minimum volume of 1 dry standard cubic meters per run).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Dioxins/furans (toxic equivalency basis).	31 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Fugitive ash	Visible emissions for no more than 5 percent of the hourly observation period.	Three 1-hour observation periods	Visible emissions test (Method 22 at 40 CFR part 60, appendix A–7).
Hydrogen chloride	200 parts per million by dry volume.	3-run average (For Method 26, collect a minimum volume of 60 liters per run. For Method 26A, collect a minimum volume of 1 dry standard cubic meter per run).	Performance test (Method 26 or 26A at 40 CFR part 60, appendix A–8).
Lead	2.0 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Mercury	0.0035 milligrams per dry standard cubic meter.	3-run average (For Method 29 and ASTM D6784–02 (Reapproved 2008),[2] collect a minimum volume of 2 dry standard cubic meters per run. For Method 30B, collect a minimum volume as specified in Method 30B at 40 CFR part 60, appendix A).	Performance test (Method 29 or 30B at 40 CFR part 60, appendix A–8) or ASTM D6784–02 (Reapproved 2008).[2]
Oxides of nitrogen	170 parts per million dry volume.	3-run average (for Method 7E, 1 hour minimum sample time per run).	Performance test (Method 7 or 7E at 40 CFR part 60, appendix A–4).
Particulate matter (filterable).	270 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters).	Performance test (Method 5 or 29 at 40 CFR part 60, appendix A–3 or appendix A–8).

TABLE 8 TO SUBPART CCCC OF PART 60—EMISSION LIMITATIONS FOR SMALL, REMOTE INCINERATORS THAT COMMENCED CONSTRUCTION AFTER JUNE 4, 2010, OR THAT COMMENCED RECONSTRUCTION OR MODIFICATION AFTER AUGUST 7, 2013—Continued

For the air pollutant	You must meet this emission limitation [1]	Using this averaging time	And determining compliance using this method
Sulfur dioxide	1.2 parts per million dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 6 or 6c at 40 CFR part 60, appendix A–4).

[1] All emission limitations are measured at 7 percent oxygen, dry basis at standard conditions. For dioxins/furans, you must meet either the Total Mass Basis limit or the toxic equivalency basis limit.

[2] Incorporated by reference, *see* § 60.17.

■ 3. Part 60 is amended by revising subpart DDDD to read as follows:

Subpart DDDD—Emissions Guidelines and Compliance Times for Commercial and Industrial Solid Waste Incineration Units

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Subpart DDDD—Emissions Guidelines and Compliance Times for Commercial and Industrial Solid Waste Incineration Units

Introduction

§ 60.2500 What is the purpose of this subpart?

This subpart establishes emission guidelines and compliance schedules for the control of emissions from commercial and industrial solid waste incineration (CISWI) units. The pollutants addressed by these emission guidelines are listed in table 2 of this subpart and tables 6 through 9 of this subpart. These emission guidelines are developed in accordance with sections 111(d) and 129 of the Clean Air Act and subpart B of this part.

§ 60.2505 Am I affected by this subpart?

(a) If you are the Administrator of an air quality program in a state or United States protectorate with one or more existing CISWI units that meet the criteria in paragraphs (b) through (d) of this section, you must submit a state plan to U.S. Environmental Protection Agency (EPA) that implements the emission guidelines contained in this subpart.

(b) You must submit a state plan to EPA by December 3, 2001 for incinerator units that commenced construction on or before November 30, 1999 and that were not modified or reconstructed after June 1, 2001.

(c) You must submit a state plan that meets the requirements of this subpart and contains the more stringent emission limit for the respective pollutant in table 6 of this subpart or table 1 of subpart CCCC of this part to EPA by February 7, 2014 for incinerators that commenced construction after November 30, 1999, but no later than June 4, 2010, or commenced modification or reconstruction after June 1, 2001 but no later than August 7, 2013.

(d) You must submit a state plan to EPA that meets the requirements of this subpart and contains the emission limits in tables 7 through 9 of this subpart by February 7, 2014, for CISWI units other than incinerator units that commenced construction on or before June 4, 2010, or commenced modification or reconstruction after June 4, 2010 but no later than August 7, 2013.

§ 60.2510 Is a state plan required for all states?

No. You are not required to submit a state plan if there are no existing CISWI units in your state, and you submit a negative declaration letter in place of the state plan.

§ 60.2515 What must I include in my state plan?

(a) You must include the nine items described in paragraphs (a)(1) through (9) of this section in your state plan:

(1) Inventory of affected CISWI units, including those that have ceased operation but have not been dismantled;

(2) Inventory of emissions from affected CISWI units in your state;

(3) Compliance schedules for each affected CISWI unit;

(4) Emission limitations, operator training and qualification requirements, a waste management plan, and operating limits for affected CISWI units that are at least as protective as the emission guidelines contained in this subpart;

(5) Performance testing, recordkeeping, and reporting requirements;

(6) Certification that the hearing on the state plan was held, a list of witnesses and their organizational affiliations, if any, appearing at the hearing, and a brief written summary of each presentation or written submission;

(7) Provision for state progress reports to EPA;

(8) Identification of enforceable state mechanisms that you selected for implementing the emission guidelines of this subpart; and

(9) Demonstration of your state's legal authority to carry out the sections 111(d) and 129 state plan.

(b) Your state plan may deviate from the format and content of the emission guidelines contained in this subpart. However, if your state plan does deviate in content, you must demonstrate that your state plan is at least as protective as the emission guidelines contained in this subpart. Your state plan must address regulatory applicability, increments of progress for retrofit, operator training and qualification, a waste management plan, emission limitations, performance testing, operating limits, monitoring, recordkeeping and reporting, and air curtain incinerator requirements.

(c) You must follow the requirements of subpart B of this part (Adoption and Submittal of State Plans for Designated Facilities) in your state plan.

§ 60.2520 Is there an approval process for my state plan?

Yes. The EPA will review your state plan according to § 60.27.

§ 60.2525 What if my state plan is not approvable?

(a) If you do not submit an approvable state plan (or a negative declaration letter) by December 2, 2002, EPA will develop a federal plan according to § 60.27 to implement the emission guidelines contained in this subpart. Owners and operators of CISWI units not covered by an approved state plan must comply with the federal plan. The federal plan is an interim action and will be automatically withdrawn when your state plan is approved.

(b) If you do not submit an approvable state plan (or a negative declaration letter) to EPA that meets the requirements of this subpart and contains the emission limits in tables 6 through 9 of this subpart for CISWI units that commenced construction on or before June 4, 2010 and incinerator or air curtain incinerator units that commenced reconstruction or modification on or after June 1, 2001 but no later than August 7, 2013, then EPA will develop a federal plan according to § 60.27 to implement the emission guidelines contained in this subpart. Owners and operators of CISWI units not covered by an approved state plan must comply with the federal plan. The federal plan is an interim action and will be automatically withdrawn when your state plan is approved.

§ 60.2530 Is there an approval process for a negative declaration letter?

No. The EPA has no formal review process for negative declaration letters. Once your negative declaration letter has been received, EPA will place a copy in the public docket and publish a notice in the **Federal Register**. If, at a later date, an existing CISWI unit is found in your state, the federal plan implementing the emission guidelines contained in this subpart would automatically apply to that CISWI unit until your state plan is approved.

§ 60.2535 What compliance schedule must I include in my state plan?

(a) For CISWI units in the incinerator subcategory and air curtain incinerators that commenced construction on or before November 30, 1999, your state plan must include compliance schedules that require CISWI units in the incinerator subcategory and air curtain incinerators to achieve final compliance as expeditiously as practicable after approval of the state plan but not later than the earlier of the two dates specified in paragraphs (a)(1) and (2) of this section:

(1) December 1, 2005; and

(2) Three years after the effective date of state plan approval.

(b) For CISWI units in the incinerator subcategory and air curtain incinerators that commenced construction after November 30, 1999, but on or before June 4, 2010 or that commenced reconstruction or modification on or after June 1, 2001 but no later than August 7, 2013, and for CISWI units in the small remote incinerator, energy recovery unit, and waste-burning kiln subcategories that commenced construction before June 4, 2010, your state plan must include compliance schedules that require CISWI units to achieve final compliance as expeditiously as practicable after approval of the state plan but not later than the earlier of the two dates specified in paragraphs (b)(1) and (2) of this section:

(1) February 7, 2018; and

(2) Three years after the effective date of State plan approval.

(c) For compliance schedules more than 1 year following the effective date of State plan approval, State plans must include dates for enforceable increments of progress as specified in § 60.2580.

§ 60.2540 Are there any State plan requirements for this subpart that apply instead of the requirements specified in subpart B?

Yes. Subpart B establishes general requirements for developing and processing section 111(d) plans. This subpart applies instead of the requirements in subpart B of this part for paragraphs (a) and (b) of this section:

(a) State plans developed to implement this subpart must be as protective as the emission guidelines contained in this subpart. State plans must require all CISWI units to comply by the dates specified in § 60.2535. This applies instead of the option for case-by-case less stringent emission standards and longer compliance schedules in § 60.24(f); and

(b) State plans developed to implement this subpart are required to include two increments of progress for the affected CISWI units. These two minimum increments are the final control plan submittal date and final compliance date in § 60.21(h)(1) and (5). This applies instead of the requirement of § 60.24(e)(1) that would require a State plan to include all five increments of progress for all CISWI units.

§ 60.2541 In lieu of a state plan submittal, are there other acceptable option(s) for a state to meet its Clean Air Act section 111(d)/129(b)(2) obligations?

Yes, a state may meet its Clean Air Act section 111(d)/129 obligations by submitting an acceptable written request for delegation of the federal plan that meets the requirements of this section. This is the only other option for a state to meet its Clean Air Act section 111(d)/129 obligations.

(a) An acceptable federal plan delegation request must include the following:

(1) A demonstration of adequate resources and legal authority to administer and enforce the federal plan;

(2) The items under § 60.2515(a)(1), (2) and (7);

(3) Certification that the hearing on the state delegation request, similar to the hearing for a state plan submittal, was held, a list of witnesses and their organizational affiliations, if any, appearing at the hearing, and a brief written summary of each presentation or written submission; and

(4) A commitment to enter into a Memorandum of Agreement with the Regional Administrator who sets forth the terms, conditions, and effective date of the delegation and that serves as the mechanism for the transfer of authority. Additional guidance and information is given in EPA's Delegation Manual, Item 7–139, Implementation and Enforcement of 111(d)(2) and 111(d)/(2)/129(b)(3) federal plans.

(b) A state with an already approved CISWI Clean Air Act section 111(d)/129 state plan is not precluded from receiving EPA approval of a delegation request for the revised federal plan, providing the requirements of paragraph (a) of this section are met, and at the time of the delegation request, the state also requests withdrawal of EPA's previous state plan approval.

(c) A state's Clean Air Act section 111(d)/129 obligations are separate from its obligations under Title V of the Clean Air Act.

§ 60.2542 What authorities will not be delegated to state, local, or tribal agencies?

The authorities listed under § 60.2030(c) will not be delegated to state, local, or tribal agencies.

§ 60.2545 Does this subpart directly affect CISWI unit owners and operators in my state?

(a) No. This subpart does not directly affect CISWI unit owners and operators in your state. However, CISWI unit owners and operators must comply with the state plan you develop to implement the emission guidelines contained in this subpart. States may choose to incorporate the model rule text directly in their state plan.

(b) If you do not submit an approvable plan to implement and enforce the guidelines contained in this subpart for CISWI units that commenced construction before November 30, 1999 by December 2, 2002, EPA will implement and enforce a federal plan, as provided in § 60.2525, to ensure that each unit within your state reaches compliance with all the provisions of this subpart by December 1, 2005.

(c) If you do not submit an approvable plan to implement and enforce the guidelines contained in this subpart by February 7, 2014, for CISWI units that commenced construction on or before June 4, 2010, EPA will implement and enforce a federal plan, as provided in § 60.2525, to ensure that each unit within your state that commenced construction on or before June 4, 2010, reaches compliance with all the provisions of this subpart by February 7, 2018.

Applicability of State Plans

§ 60.2550 What CISWI units must I address in my state plan?

(a) Your state plan must address incineration units that meet all three criteria described in paragraphs (a)(1) through (3) of this section:

(1) CISWI units and air curtain incinerators in your state that commenced construction on or before June 4, 2010, or commenced modification or reconstruction after June 4, 2010 but no later than August 7, 2013;

(2) Incineration units that meet the definition of a CISWI unit as defined in § 60.2875; and

(3) Incineration units not exempt under § 60.2555.

(b) If the owner or operator of a CISWI unit or air curtain incinerator makes changes that meet the definition of modification or reconstruction after August 7, 2013, the CISWI unit becomes subject to subpart CCCC of this part and the state plan no longer applies to that unit.

(c) If the owner or operator of a CISWI unit makes physical or operational changes to an existing CISWI unit primarily to comply with your state plan, subpart CCCC of this part does not apply to that unit. Such changes do not qualify as modifications or reconstructions under subpart CCCC of this part.

§ 60.2555 What combustion units are exempt from my state plan?

This subpart exempts the types of units described in paragraphs (a), (c) through (i), (m), and (n) of this section, but some units are required to provide notifications. Air curtain incinerators are exempt from the requirements in this subpart except for the provisions in §§ 60.2805, 60.2860, and 60.2870:

(a) *Pathological waste incineration units.* Incineration units burning 90 percent or more by weight (on a calendar quarter basis and excluding the weight of auxiliary fuel and combustion air) of pathological waste, low-level radioactive waste, and/or chemotherapeutic waste as defined in § 60.2875 are not subject to this subpart if you meet the two requirements specified in paragraphs (a)(1) and (2) of this section:

(1) Notify the Administrator that the unit meets these criteria; and

(2) Keep records on a calendar quarter basis of the weight of pathological waste, low-level radioactive waste, and/or chemotherapeutic waste burned, and the weight of all other fuels and wastes burned in the unit.

(b) [Reserved]

(c) *Municipal waste combustion units.* Incineration units that are subject to subpart Ea of this part (Standards of Performance for Municipal Waste Combustors); subpart Eb of this part (Standards of Performance for Large Municipal Waste Combustors); subpart Cb of this part (Emission Guidelines and Compliance Time for Large Municipal Combustors); AAAA of this part (Standards of Performance for Small Municipal Waste Combustion Units); or subpart BBBB of this part (Emission Guidelines for Small Municipal Waste Combustion Units).

(d) *Medical waste incineration units.* Incineration units regulated under subpart Ec of this part (Standards of Performance for Hospital/Medical/Infectious Waste Incinerators for Which Construction is Commenced After June 20, 1996) or subpart Ca of this part (Emission Guidelines and Compliance Times for Hospital/Medical/Infectious Waste Incinerators).

(e) *Small power production facilities.* Units that meet the three requirements specified in paragraphs (e)(1) through (4) of this section:

(1) The unit qualifies as a small power-production facility under section 3(17)(C) of the Federal Power Act (16 U.S.C. 796(17)(C));

(2) The unit burns homogeneous waste (not including refuse-derived fuel) to produce electricity;

(3) You submit documentation to the Administrator notifying the Agency that the qualifying small power production facility is combusting homogenous waste; and

(4) You maintain the records specified in § 60.2740(v).

(f) *Cogeneration facilities.* Units that meet the three requirements specified in paragraphs (f)(1) through (4) of this section:

(1) The unit qualifies as a cogeneration facility under section 3(18)(B) of the Federal Power Act (16 U.S.C. 796(18)(B));

(2) The unit burns homogeneous waste (not including refuse-derived fuel) to produce electricity and steam or other forms of energy used for industrial, commercial, heating, or cooling purposes;

(3) You submit documentation to the Administrator notifying the Agency that the qualifying cogeneration facility is combusting homogenous waste; and

(4) You maintain the records specified in § 60.2740(w).

(g) *Hazardous waste combustion units.* Units for which you are required to get a permit under section 3005 of the Solid Waste Disposal Act.

(h) *Materials recovery units.* Units that combust waste for the primary purpose of recovering metals, such as primary and secondary smelters.

(i) *Air curtain incinerators.* Air curtain incinerators that burn only the materials listed in paragraphs (i)(1) through (3) of this section are only required to meet the requirements under § 60.2805 and under "Air Curtain Incinerators" (§§ 60.2810 through 60.2870):

(1) 100 percent wood waste;

(2) 100 percent clean lumber; and

(3) 100 percent mixture of only wood waste, clean lumber, and/or yard waste.

(j)–(l) [Reserved]

(m) *Sewage treatment plants* . Incineration units regulated under subpart O of this part (Standards of Performance for Sewage Treatment Plants).

(n) *Sewage sludge incineration units.* Incineration units combusting sewage sludge for the purpose of reducing the volume of the sewage sludge by removing combustible matter that are subject to subpart LLLL of this part (Standards of Performance for New Sewage Sludge Incineration Units) or subpart MMMM of this part (Emission Guidelines and Compliance Times for Existing Sewage Sludge Incineration Units).

(o) *Other solid waste incineration units.* Incineration units that are subject to subpart EEEE of this part (Standards of Performance for Other Solid Waste Incineration Units for Which Construction is Commenced After December 9, 2004, or for Which Modification or Reconstruction is Commenced on or After June 16, 2006) or subpart FFFF of this part (Emission Guidelines and Compliance Times for Other Solid Waste Incineration Units That Commenced Construction On or Before December 9, 2004).

Use of Model Rule

§ 60.2560 What is the "model rule" in this subpart?

(a) The model rule is the portion of these emission guidelines (§§ 60.2575 through 60.2875) that addresses the regulatory requirements applicable to CISWI units. The model rule provides these requirements in regulation format. You must develop a state plan that is at least as protective as the model rule. You may use the model rule language as part of your state plan. Alternative language may be used in your state plan if you demonstrate that the alternative language is at least as protective as the model rule contained in this subpart.

(b) In the model rule of §§ 60.2575 to 60.2875, "you" means the owner or operator of a CISWI unit.

§ 60.2565 How does the model rule relate to the required elements of my state plan?

Use the model rule to satisfy the state plan requirements specified in § 60.2515(a)(4) and (5).

§ 60.2570 What are the principal components of the model rule?

The model rule contains the eleven major components listed in paragraphs (a) through (k) of this section:

(a) Increments of progress toward compliance;

(b) Waste management plan;

(c) Operator training and qualification;

(d) Emission limitations and operating limits;

(e) Performance testing;

(f) Initial compliance requirements;

(g) Continuous compliance requirements;

(h) Monitoring;

(i) Recordkeeping and reporting;

(j) Definitions; and

(k) Tables.

Model Rule—Increments of Progress

§ 60.2575 What are my requirements for meeting increments of progress and achieving final compliance?

If you plan to achieve compliance more than 1 year following the effective date of state plan approval, you must meet the two increments of progress specified in paragraphs (a) and (b) of this section:

(a) Submit a final control plan; and

(b) Achieve final compliance.

§ 60.2580 When must I complete each increment of progress?

Table 1 of this subpart specifies compliance dates for each of the increments of progress.

§ 60.2585 What must I include in the notifications of achievement of increments of progress?

Your notification of achievement of increments of progress must include the three items specified in paragraphs (a) through (c) of this section:

(a) Notification that the increment of progress has been achieved;

(b) Any items required to be submitted with each increment of progress; and

(c) Signature of the owner or operator of the CISWI unit.

§ 60.2590 When must I submit the notifications of achievement of increments of progress?

Notifications for achieving increments of progress must be postmarked no later than 10 business days after the compliance date for the increment.

§ 60.2595 What if I do not meet an increment of progress?

If you fail to meet an increment of progress, you must submit a notification to the Administrator postmarked within 10 business days after the date for that increment of progress in table 1 of this subpart. You must inform the Administrator that you did not meet the increment, and you must continue to submit reports each subsequent calendar month until the increment of progress is met.

§ 60.2600 How do I comply with the increment of progress for submittal of a control plan?

For your control plan increment of progress, you must satisfy the two requirements specified in paragraphs (a) and (b) of this section:

(a) Submit the final control plan that includes the five items described in paragraphs (a)(1) through (5) of this section:

(1) A description of the devices for air pollution control and process changes that you will use to comply with the emission limitations and other requirements of this subpart;

(2) The type(s) of waste to be burned;

(3) The maximum design waste burning capacity;

(4) The anticipated maximum charge rate; and

(5) If applicable, the petition for site-specific operating limits under § 60.2680.

(b) Maintain an onsite copy of the final control plan.

§ 60.2605 How do I comply with the increment of progress for achieving final compliance?

For the final compliance increment of progress, you must complete all process changes and retrofit construction of control devices, as specified in the final control plan, so that, if the affected CISWI unit is brought online, all necessary process changes and air pollution control devices would operate as designed.

§ 60.2610 What must I do if I close my CISWI unit and then restart it?

(a) If you close your CISWI unit but will restart it prior to the final compliance date in your state plan, you must meet the increments of progress specified in § 60.2575.

(b) If you close your CISWI unit but will restart it after your final compliance date, you must complete emission control retrofits and meet the emission limitations and operating limits on the date your unit restarts operation.

§ 60.2615 What must I do if I plan to permanently close my CISWI unit and not restart it?

If you plan to close your CISWI unit rather than comply with the state plan, submit a closure notification, including the date of closure, to the Administrator by the date your final control plan is due.

Model Rule—Waste Management Plan

§ 60.2620 What is a waste management plan?

A waste management plan is a written plan that identifies both the feasibility and the methods used to reduce or separate certain components of solid waste from the waste stream in order to reduce or eliminate toxic emissions from incinerated waste.

§ 60.2625 When must I submit my waste management plan?

You must submit a waste management plan no later than the date specified in table 1 of this subpart for submittal of the final control plan.

§ 60.2630 What should I include in my waste management plan?

A waste management plan must include consideration of the reduction or separation of waste-stream elements such as paper, cardboard, plastics, glass, batteries, or metals; or the use of recyclable materials. The plan must identify any additional waste management measures, and the source must implement those measures considered practical and feasible, based on the effectiveness of waste management measures already in place, the costs of additional measures, the emissions reductions expected to be achieved, and any other environmental or energy impacts they might have.

Model Rule—Operator Training and Qualification

§ 60.2635 What are the operator training and qualification requirements?

(a) No CISWI unit can be operated unless a fully trained and qualified CISWI unit operator is accessible, either at the facility or can be at the facility within 1 hour. The trained and qualified CISWI unit operator may operate the CISWI unit directly or be the direct supervisor of one or more other plant personnel who operate the unit. If all qualified CISWI unit operators are temporarily not accessible, you must follow the procedures in § 60.2665.

(b) Operator training and qualification must be obtained through a state-approved program or by completing the requirements included in paragraph (c) of this section.

(c) Training must be obtained by completing an incinerator operator training course that includes, at a minimum, the three elements described in paragraphs (c)(1) through (3) of this section:

(1) Training on the eleven subjects listed in paragraphs (c)(1)(i) through (xi) of this section:

(i) Environmental concerns, including types of emissions;

(ii) Basic combustion principles, including products of combustion;

(iii) Operation of the specific type of incinerator to be used by the operator, including proper startup, waste charging, and shutdown procedures;

(iv) Combustion controls and monitoring;

(v) Operation of air pollution control equipment and factors affecting performance (if applicable);

(vi) Inspection and maintenance of the incinerator and air pollution control devices;

(vii) Actions to prevent and correct malfunctions or to prevent conditions that may lead to malfunctions;

(viii) Bottom and fly ash characteristics and handling procedures;

(ix) Applicable federal, state, and local regulations, including Occupational Safety and Health Administration workplace standards;

(x) Pollution prevention; and

(xi) Waste management practices.

(2) An examination designed and administered by the instructor.

(3) Written material covering the training course topics that can serve as reference material following completion of the course.

§ 60.2640 When must the operator training course be completed?

The operator training course must be completed by the later of the three dates specified in paragraphs (a) through (c) of this section:

(a) The final compliance date (Increment 2);

(b) Six months after CISWI unit startup; and

(c) Six months after an employee assumes responsibility for operating the CISWI unit or assumes responsibility for supervising the operation of the CISWI unit.

§ 60.2645 How do I obtain my operator qualification?

(a) You must obtain operator qualification by completing a training course that satisfies the criteria under § 60.2635(b).

(b) Qualification is valid from the date on which the training course is completed and the operator successfully passes the examination required under § 60.2635(c)(2).

§ 60.2650 How do I maintain my operator qualification?

To maintain qualification, you must complete an annual review or refresher course covering, at a minimum, the five topics described in paragraphs (a) through (e) of this section:

(a) Update of regulations;

(b) Incinerator operation, including startup and shutdown procedures, waste charging, and ash handling;

(c) Inspection and maintenance;

(d) Prevention and correction of malfunctions or conditions that may lead to malfunction; and

(e) Discussion of operating problems encountered by attendees.

§ 60.2655 How do I renew my lapsed operator qualification?

You must renew a lapsed operator qualification by one of the two methods specified in paragraphs (a) and (b) of this section:

(a) For a lapse of less than 3 years, you must complete a standard annual refresher course described in § 60.2650; and

(b) For a lapse of 3 years or more, you must repeat the initial qualification requirements in § 60.2645(a).

§ 60.2660 What site-specific documentation is required?

(a) Documentation must be available at the facility and readily accessible for all CISWI unit operators that addresses the ten topics described in paragraphs (a)(1) through (10) of this section. You must maintain this information and the training records required by paragraph (c) of this section in a manner that they can be readily accessed and are suitable for inspection upon request:

(1) Summary of the applicable standards under this subpart;

(2) Procedures for receiving, handling, and charging waste;

(3) Incinerator startup, shutdown, and malfunction procedures;

(4) Procedures for maintaining proper combustion air supply levels;

(5) Procedures for operating the incinerator and associated air pollution control systems within the standards established under this subpart;

(6) Monitoring procedures for demonstrating compliance with the incinerator operating limits;

(7) Reporting and recordkeeping procedures;

(8) The waste management plan required under §§ 60.2620 through 60.2630;

(9) Procedures for handling ash; and

(10) A list of the wastes burned during the performance test.

(b) You must establish a program for reviewing the information listed in paragraph (a) of this section with each incinerator operator:

(1) The initial review of the information listed in paragraph (a) of this section must be conducted by the later of the three dates specified in paragraphs (b)(1)(i) through (iii) of this section:

(i) The final compliance date (Increment 2);

(ii) Six months after CISWI unit startup; and

(iii) Six months after being assigned to operate the CISWI unit.

(2) Subsequent annual reviews of the information listed in paragraph (a) of this section must be conducted no later than 12 months following the previous review.

(c) You must also maintain the information specified in paragraphs (c)(1) through (3) of this section:

(1) Records showing the names of CISWI unit operators who have completed review of the information in § 60.2660(a) as required by § 60.2660(b), including the date of the initial review and all subsequent annual reviews;

(2) Records showing the names of the CISWI operators who have completed the operator training requirements under § 60.2635, met the criteria for qualification under § 60.2645, and maintained or renewed their qualification under § 60.2650 or § 60.2655. Records must include documentation of training, the dates of the initial refresher training, and the dates of their qualification and all subsequent renewals of such qualifications; and

(3) For each qualified operator, the phone and/or pager number at which they can be reached during operating hours.

§ 60.2665 What if all the qualified operators are temporarily not accessible?

If all qualified operators are temporarily not accessible (*i.e.,* not at the facility and not able to be at the facility within 1 hour), you must meet one of the two criteria specified in paragraphs (a) and (b) of this section, depending on the length of time that a qualified operator is not accessible:

(a) When all qualified operators are not accessible for more than 8 hours, but less than 2 weeks, the CISWI unit may be operated by other plant personnel familiar with the operation of the CISWI unit who have completed a review of the information specified in § 60.2660(a) within the past 12 months. However, you must record the period when all qualified operators were not accessible and include this deviation in the annual report as specified under § 60.2770;

(b) When all qualified operators are not accessible for 2 weeks or more, you must take the two actions that are described in paragraphs (b)(1) and (2) of this section:

(1) Notify the Administrator of this deviation in writing within 10 days. In the notice, state what caused this deviation, what you are doing to ensure that a qualified operator is accessible, and when you anticipate that a qualified operator will be accessible; and

(2) Submit a status report to the Administrator every 4 weeks outlining what you are doing to ensure that a qualified operator is accessible, stating when you anticipate that a qualified operator will be accessible and requesting approval from the Administrator to continue operation of the CISWI unit. You must submit the first status report 4 weeks after you notify the Administrator of the deviation under paragraph (b)(1) of this section. If the Administrator notifies you that your request to continue operation of the CISWI unit is disapproved, the CISWI unit may continue operation for 90 days, then must cease operation. Operation of the unit may resume if you meet the two requirements in paragraphs (b)(2)(i) and (ii) of this section:

(i) A qualified operator is accessible as required under § 60.2635(a); and

(ii) You notify the Administrator that a qualified operator is accessible and that you are resuming operation.

Model Rule—Emission Limitations and Operating Limits

§ 60.2670 What emission limitations must I meet and by when?

(a) You must meet the emission limitations for each CISWI unit, including bypass stack or vent, specified in table 2 of this subpart or tables 6 through 9 of this subpart by the final compliance date under the approved state plan, federal plan, or delegation, as applicable. The emission limitations apply at all times the unit is operating including and not limited to startup, shutdown, or malfunction.

(b) Units that do not use wet scrubbers must maintain opacity to less than or equal to the percent opacity (three 1-hour blocks consisting of ten 6-minute average opacity values) specified in table 2 of this subpart, as applicable.

§ 60.2675 What operating limits must I meet and by when?

(a) If you use a wet scrubber(s) to comply with the emission limitations, you must establish operating limits for up to four operating parameters (as specified in table 3 of this subpart) as described in paragraphs (a)(1) through (4) of this section during the initial performance test:

(1) Maximum charge rate, calculated using one of the two different procedures in paragraph (a)(1)(i) or (ii) of this section, as appropriate:

(i) For continuous and intermittent units, maximum charge rate is 110 percent of the average charge rate measured during the most recent performance test demonstrating compliance with all applicable emission limitations; and

(ii) For batch units, maximum charge rate is 110 percent of the daily charge rate measured during the most recent performance test demonstrating compliance with all applicable emission limitations.

(2) Minimum pressure drop across the wet particulate matter scrubber, which is calculated as the lowest 1-hour average pressure drop across the wet scrubber measured during the most recent performance test demonstrating compliance with the particulate matter emission limitations; or minimum amperage to the wet scrubber, which is calculated as the lowest 1-hour average amperage to the wet scrubber measured during the most recent performance test demonstrating compliance with the particulate matter emission limitations.

(3) Minimum scrubber liquid flow rate, which is calculated as the lowest 1-hour average liquid flow rate at the inlet to the wet acid gas or particulate matter scrubber measured during the most recent performance test demonstrating compliance with all applicable emission limitations.

(4) Minimum scrubber liquor pH, which is calculated as the lowest 1-hour average liquor pH at the inlet to the wet acid gas scrubber measured during the most recent performance test demonstrating compliance with the HCl emission limitation.

(b) You must meet the operating limits established during the initial performance test on the date the initial performance test is required or completed (whichever is earlier). You must conduct an initial performance evaluation of each continuous monitoring system and continuous parameter monitoring system within 60 days of installation of the monitoring system.

(c) If you use a fabric filter to comply with the emission limitations and you do not use a PM CPMS for monitoring PM compliance, you must operate each fabric filter system such that the bag leak detection system alarm does not sound more than 5 percent of the operating time during a 6-month period. In calculating this operating time percentage, if inspection of the fabric filter demonstrates that no corrective action is required, no alarm time is counted. If corrective action is required, each alarm shall be counted as a minimum of 1 hour. If you take longer than 1 hour to initiate corrective action, the alarm time shall be counted as the actual amount of time taken by you to initiate corrective action.

(d) If you use an electrostatic precipitator to comply with the emission limitations and you do not use a PM CPMS for monitoring PM compliance, you must measure the (secondary) voltage and amperage of the electrostatic precipitator collection plates during the particulate matter performance test. Calculate the average electric power value (secondary voltage × secondary current = secondary electric power) for each test run. The operating limit for the electrostatic precipitator is calculated as the lowest 1-hour average secondary electric power measured during the most recent performance test demonstrating compliance with the particulate matter emission limitations.

(e) If you use activated carbon sorbent injection to comply with the emission limitations, you must measure the sorbent flow rate during the performance testing. The operating limit for the carbon sorbent injection is calculated as the lowest 1-hour average sorbent flow rate measured during the most recent performance test demonstrating compliance with the mercury emission limitations. For energy recovery units, when your unit operates at lower loads, multiply your sorbent injection rate by the load fraction, as defined in this subpart, to determine the required injection rate (*e.g.*, for 50 percent load, multiply the injection rate operating limit by 0.5).

(f) If you use selective noncatalytic reduction to comply with the emission limitations, you must measure the charge rate, the secondary chamber temperature (if applicable to your CISWI unit), and the reagent flow rate during the nitrogen oxides performance testing. The operating limits for the selective noncatalytic reduction are calculated as the highest 1-hour average charge rate, lowest secondary chamber temperature, and lowest reagent flow rate measured during the most recent performance test demonstrating compliance with the nitrogen oxides emission limitations.

(g) If you use a dry scrubber to comply with the emission limitations, you must measure the injection rate of each sorbent during the performance testing. The operating limit for the injection rate of each sorbent is calculated as the lowest 1-hour average injection rate of each sorbent measured during the most recent performance test demonstrating compliance with the hydrogen chloride emission limitations. For energy recovery units, when your unit operates at lower loads, multiply your sorbent injection rate by the load fraction, as defined in this subpart, to determine the required injection rate (*e.g.*, for 50 percent load, multiply the injection rate operating limit by 0.5).

(h) If you do not use a wet scrubber, electrostatic precipitator, or fabric filter to comply with the emission limitations, and if you do not determine compliance with your particulate matter emission limitation with either a particulate matter CEMS or a particulate matter CPMS, you must maintain opacity to less than or equal to ten percent opacity (1-hour block average).

(i) If you use a PM CPMS to demonstrate compliance, you must establish your PM CPMS operating limit and determine compliance with it according to paragraphs (i)(1) through (5) of this section:

(1) During the initial performance test or any such subsequent performance test that demonstrates compliance with the PM limit, record all hourly average output values (milliamps, or the digital signal equivalent) from the PM CPMS for the periods corresponding to the test runs (*e.g.*, three 1-hour average PM CPMS output values for three 1-hour test runs):

(i) Your PM CPMS must provide a 4–20 milliamp output, or the digital signal equivalent, and the establishment of its relationship to manual reference method measurements must be determined in units of milliamps or digital bits;

(ii) Your PM CPMS operating range must be capable of reading PM concentrations from zero to a level equivalent to at least two times your allowable emission limit. If your PM CPMS is an auto-ranging instrument capable of multiple scales, the primary range of the instrument must be capable of reading PM concentration from zero to a level equivalent to two times your allowable emission limit; and

(iii) During the initial performance test or any such subsequent performance test that demonstrates compliance with the PM limit, record and average all milliamp output values, or their digital equivalent, from the PM CPMS for the periods corresponding to the compliance test runs (*e.g.*, average all your PM CPMS output values for three corresponding 2-hour Method 5I test runs).

(2) If the average of your three PM performance test runs are below 75 percent of your PM emission limit, you must calculate an operating limit by establishing a relationship of PM CPMS signal to PM concentration using the PM CPMS instrument zero, the average PM CPMS output values corresponding to the three compliance test runs, and the average PM concentration from the Method 5 or performance test with the procedures in (i)(1)through (5) of this section:

(i) Determine your instrument zero output with one of the following procedures:

(A) Zero point data for *in-situ* instruments should be obtained by removing the instrument from the stack and monitoring ambient air on a test bench;

(B) Zero point data for extractive instruments should be obtained by removing the extractive probe from the stack and drawing in clean ambient air;

(C) The zero point can also can be established obtained by performing manual reference method measurements when the flue gas is free of PM emissions or contains very low PM concentrations (*e.g.*, when your process is not operating, but the fans are operating or your source is combusting only natural gas) and plotting these with the compliance data to find the zero intercept; and

(D) If none of the steps in paragraphs (i)(2)(i)(A) through (C) of this section are possible, you must use a zero output value provided by the manufacturer.

(ii) Determine your PM CPMS instrument average in milliamps, or the digital equivalent, and the average of your corresponding three PM compliance test runs, using equation 1:

$$\frac{1}{n}\sum_{i=1}^{n} X_1, \quad \frac{1}{n}\sum_{i=1}^{n} Y_1 \qquad \text{(Eq. 1)}$$

Where:

X_1 = the PM CPMS output data points for the three runs constituting the performance test,

Y_1 = the PM concentration value for the three runs constituting the performance test, and

n = the number of data points.

(iii) With your instrument zero expressed in milliamps, or the digital equivalent, your three run average PM CPMS milliamp value, or its digital equivalent, and your three run average PM concentration from your three compliance tests, determine a relationship of mg/dscm per milliamp or digital signal equivalent, with equation 2:

$$R = \frac{Y_1}{(X_1 - z)} \qquad \text{(Eq. 2)}$$

Where:

R = the relative mg/dscm per milliamp, or the digital equivalent, for your PM CPMS,

Y_1 = the three run average mg/dscm PM concentration,

X_1 = the three run average milliamp output, or the digital equivalent, from you PM CPMS, and

z = the milliamp or digital signal equivalent of your instrument zero determined from paragraph (i)(2)(i) of this section.

(iv) Determine your source specific 30-day rolling average operating limit using the mg/dscm per milliamp value, or per digital signal equivalent, from equation 2 in equation 3, below. This sets your operating limit at the PM CPMS output value corresponding to 75 percent of your emission limit:

$$O_l - z + \frac{0.75(L)}{R} \qquad \text{(Eq. 3)}$$

Where:

O_l = the operating limit for your PM CPMS on a 30-day rolling average, in milliamps or their digital signal equivalent,

L = your source emission limit expressed in mg/dscm,

z = your instrument zero in milliamps or digital equivalent, determined from paragraph (i)(2)(i) of this section, and

R = the relative mg/dscm per milliamp, or per digital signal output equivalent, for your PM CPMS, from equation 2.

(3) If the average of your three PM compliance test runs is at or above 75 percent of your PM emission limit you must determine your operating limit by averaging the PM CPMS milliamp or digital signal output corresponding to your three PM performance test runs that demonstrate compliance with the emission limit using equation 4 and you must submit all compliance test and PM CPMS data according to the reporting requirements in paragraph (i)(5) of this section:

$$O_h = \frac{1}{n}\sum_{i=1}^{n} X_1 \qquad \text{(Eq. 4)}$$

Where:

X_1 = the PM CPMS data points for all runs i,

n = the number of data points, and

O_h = your site specific operating limit, in milliamps or digital signal equivalent.

(4) To determine continuous compliance, you must record the PM CPMS output data for all periods when the process is operating and the PM CPMS is not out-of-control. You must demonstrate continuous compliance by using all quality-assured hourly average data collected by the PM CPMS for all operating hours to calculate the arithmetic average operating parameter in units of the operating limit (*e.g.*, milliamps or digital signal bits, PM concentration, raw data signal) on a 30-day rolling average basis.

(5) For PM performance test reports used to set a PM CPMS operating limit, the electronic submission of the test report must also include the make and model of the PM CPMS instrument, serial number of the instrument, analytical principle of the instrument (*e.g.*, beta attenuation), span of the instruments primary analytical range, milliamp or digital signal value equivalent to the instrument zero output, technique by which this zero value was determined, and the average milliamp or digital signals corresponding to each PM compliance test run.

§ 60.2680 What if I do not use a wet scrubber, fabric filter, activated carbon injection, selective noncatalytic reduction, an electrostatic precipitator, or a dry scrubber to comply with the emission limitations?

(a) If you use an air pollution control device other than a wet scrubber, activated carbon injection, selective noncatalytic reduction, fabric filter, an electrostatic precipitator, or a dry scrubber or limit emissions in some other manner, including mass balances, to comply with the emission limitations under § 60.2670, you must petition the EPA Administrator for specific operating limits to be established during the initial performance test and continuously monitored thereafter. You must submit the petition at least sixty days before the performance test is scheduled to begin. Your petition must include the five items listed in paragraphs (a)(1) through (5) of this section:

(1) Identification of the specific parameters you propose to use as additional operating limits;

(2) A discussion of the relationship between these parameters and emissions of regulated pollutants, identifying how emissions of regulated pollutants change with changes in these parameters and how limits on these parameters will serve to limit emissions of regulated pollutants;

(3) A discussion of how you will establish the upper and/or lower values for these parameters which will establish the operating limits on these parameters;

(4) A discussion identifying the methods you will use to measure and the instruments you will use to monitor these parameters, as well as the relative accuracy and precision of these methods and instruments; and

(5) A discussion identifying the frequency and methods for recalibrating the instruments you will use for monitoring these parameters.

(b) [Reserved]

Model Rule—Performance Testing

§ 60.2690 How do I conduct the initial and annual performance test?

(a) All performance tests must consist of a minimum of three test runs conducted under conditions representative of normal operations.

(b) You must document that the waste burned during the performance test is representative of the waste burned under normal operating conditions by maintaining a log of the quantity of waste burned (as required in § 60.2740(b)(1)) and the types of waste burned during the performance test.

(c) All performance tests must be conducted using the minimum run duration specified in tables 2 and 6 through 9 of this subpart.

(d) Method 1 of appendix A of this part must be used to select the sampling location and number of traverse points.

(e) Method 3A or 3B of appendix A of this part must be used for gas composition analysis, including measurement of oxygen concentration. Method 3A or 3B of appendix A of this part must be used simultaneously with each method.

(f) All pollutant concentrations, except for opacity, must be adjusted to 7 percent oxygen using equation 5 of this section:

$$C_{adj} = C_{meas}\ (20.9-7)/(20.9-\%O_2) \qquad \text{(Eq. 5)}$$

Where:

C_{adj} = pollutant concentration adjusted to 7 percent oxygen;

C_{meas} = pollutant concentration measured on a dry basis;

$(20.9 - 7)$ = 20.9 percent oxygen − 7 percent oxygen (defined oxygen correction basis);

20.9 = oxygen concentration in air, percent; and

$\%O_2$ = oxygen concentration measured on a dry basis, percent.

(g) You must determine dioxins/furans toxic equivalency by following the procedures in paragraphs (g)(1) through (4) of this section:

(1) Measure the concentration of each dioxin/furan tetra- through octa-isomer emitted using EPA Method 23 at 40 CFR part 60, appendix A;

(2) Quantify isomers meeting identification criteria 2, 3, 4, and 5 in Section 5.3.2.5 of Method 23, regardless of whether the isomers meet identification criteria 1 and 7. You must quantify the isomers per Section 9.0 of Method 23. [Note: You may reanalyze the sample aliquot or split to reduce the number of isomers not meeting identification criteria 1 or 7 of Section 5.3.2.5.];

(3) For each dioxin/furan (tetra- through octa-chlorinated) isomer measured in accordance with paragraph (g)(1) and (2) of this section, multiply the isomer concentration by its corresponding toxic equivalency factor specified in table 4 of this subpart; and

(4) Sum the products calculated in accordance with paragraph (g)(3) of this section to obtain the total concentration of dioxins/furans emitted in terms of toxic equivalency.

(h) Method 22 at 40 CFR part 60, appendix A–7 must be used to determine compliance with the fugitive ash emission limit in table 2 of this subpart or tables 6 through 9 of this subpart.

(i) If you have an applicable opacity operating limit, you must determine compliance with the opacity limit using Method 9 at 40 CFR part 60, appendix A–4, based on three 1-hour blocks consisting of ten 6-minute average opacity values, unless you are required to install a continuous opacity monitoring system, consistent with § 60.2710 and § 60.2730.

(j) You must determine dioxins/furans total mass basis by following the procedures in paragraphs (j)(1) through (3) of this section:

(1) Measure the concentration of each dioxin/furan tetra- through octa-chlorinated isomer emitted using EPA Method 23 at 40 CFR part 60, appendix A–7;

(2) Quantify isomers meeting identification criteria 2, 3, 4, and 5 in Section 5.3.2.5 of Method 23, regardless of whether the isomers meet identification criteria 1 and 7. You must quantify the isomers per Section 9.0 of Method 23. (Note: You may reanalyze the sample aliquot or split to reduce the number of isomers not meeting identification criteria 1 or 7 of Section 5.3.2.5.); and

(3) Sum the quantities measured in accordance with paragraphs (j)(1) and (2) of this section to obtain the total concentration of dioxins/furans emitted in terms of total mass basis.

§ 60.2695 How are the performance test data used?

You use results of performance tests to demonstrate compliance with the emission limitations in table 2 of this subpart or tables 6 through 9 of this subpart.

Model Rule—Initial Compliance Requirements

§ 60.2700 How do I demonstrate initial compliance with the amended emission limitations and establish the operating limits?

You must conduct a performance test, as required under §§ 60.2670 and 60.2690, to determine compliance with the emission limitations in table 2 of this subpart and tables 6 through 9 of this subpart, to establish compliance with any opacity operating limits in § 60.2675, to establish the kiln-specific emission limit in § 60.2710(y), as applicable, and to establish operating limits using the procedures in § 60.2675 or § 60.2680. The performance test must be conducted using the test methods listed in table 2 of this subpart and tables 6 through 9 of this subpart and the procedures in § 60.2690. The use of the bypass stack during a performance test shall invalidate the performance test. You must conduct a performance evaluation of each continuous monitoring system within 60 days of installation of the monitoring system.

§ 60.2705 By what date must I conduct the initial performance test?

(a) The initial performance test must be conducted no later than 180 days after your final compliance date. Your final compliance date is specified in table 1 of this subpart.

(b) If you commence or recommence combusting a solid waste at an existing combustion unit at any commercial or industrial facility and you conducted a test consistent with the provisions of this subpart while combusting the given solid waste within the 6 months preceding the reintroduction of that solid waste in the combustion chamber, you do not need to retest until 6 months from the date you reintroduce that solid waste.

(c) If you commence or recommence combusting a solid waste at an existing combustion unit at any commercial or industrial facility and you have not conducted a performance test consistent with the provisions of this subpart while combusting the given solid waste within the 6 months preceding the reintroduction of that solid waste in the combustion chamber, you must conduct a performance test within 60 days from the date you reintroduce solid waste.

§ 60.2706 By what date must I conduct the initial air pollution control device inspection?

(a) The initial air pollution control device inspection must be conducted within 60 days after installation of the control device and the associated CISWI unit reaches the charge rate at which it will operate, but no later than 180 days after the final compliance date for meeting the amended emission limitations.

(b) Within 10 operating days following an air pollution control device inspection, all necessary repairs must be completed unless the owner or operator obtains written approval from the state agency establishing a date whereby all necessary repairs of the designated facility must be completed.

Model Rule—Continuous Compliance Requirements

§ 60.2710 How do I demonstrate continuous compliance with the amended emission limitations and the operating limits?

(a) *Compliance with standards.* (1) The emission standards and operating requirements set forth in this subpart apply at all times.

(2) If you cease combusting solid waste you may opt to remain subject to the provisions of this subpart. Consistent with the definition of CISWI unit, you are subject to the requirements of this subpart at least 6 months following the last date of solid waste combustion. Solid waste combustion is ceased when solid waste is not in the combustion chamber (*i.e.,* the solid waste feed to the combustor has been cut off for a period of time not less than the solid waste residence time).

(3) If you cease combusting solid waste you must be in compliance with any newly applicable standards on the effective date of the waste-to-fuel switch. The effective date of the waste-to-fuel switch is a date selected by you, that must be at least 6 months from the date that you ceased combusting solid waste, consistent with § 60.2710(a)(2). Your source must remain in compliance

with this subpart until the effective date of the waste-to-fuel switch.

(4) If you own or operate an existing commercial or industrial combustion unit that combusted a fuel or non-waste material, and you commence or recommence combustion of solid waste, you are subject to the provisions of this subpart as of the first day you introduce or reintroduce solid waste to the combustion chamber, and this date constitutes the effective date of the fuel-to-waste switch. You must complete all initial compliance demonstrations for any Section 112 standards that are applicable to your facility before you commence or recommence combustion of solid waste. You must provide 30 days prior notice of the effective date of the waste-to-fuel switch. The notification must identify:

(i) The name of the owner or operator of the CISWI unit, the location of the source, the emissions unit(s) that will cease burning solid waste, and the date of the notice;

(ii) The currently applicable subcategory under this subpart, and any 40 CFR part 63 subpart and subcategory that will be applicable after you cease combusting solid waste;

(iii) The fuel(s), non-waste material(s) and solid waste(s) the CISWI unit is currently combusting and has combusted over the past 6 months, and the fuel(s) or non-waste materials the unit will commence combusting;

(iv) The date on which you became subject to the currently applicable emission limits;

(v) The date upon which you will cease combusting solid waste, and the date (if different) that you intend for any new requirements to become applicable (*i.e.*, the effective date of the waste-to-fuel switch), consistent with paragraphs (a)(2) and (3) of this section.

(5) All air pollution control equipment necessary for compliance with any newly applicable emissions limits which apply as a result of the cessation or commencement or recommencement of combusting solid waste must be installed and operational as of the effective date of the waste-to-fuel, or fuel-to-waste switch.

(6) All monitoring systems necessary for compliance with any newly applicable monitoring requirements which apply as a result of the cessation or commencement or recommencement of combusting solid waste must be installed and operational as of the effective date of the waste-to-fuel, or fuel-to-waste switch. All calibration and drift checks must be performed as of the effective date of the waste-to-fuel, or fuel-to-waste switch. Relative accuracy tests must be performed as of the performance test deadline for PM CEMS (if PM CEMS are elected to demonstrate continuous compliance with the particulate matter emission limits). Relative accuracy testing for other CEMS need not be repeated if that testing was previously performed consistent with section 112 monitoring requirements or monitoring requirements under this subpart.

(b) You must conduct an annual performance test for the pollutants listed in table 2 of this subpart or tables 6 through 9 of this subpart and opacity for each CISWI unit as required under § 60.2690. The annual performance test must be conducted using the test methods listed in table 2 of this subpart or tables 6 through 9 of this subpart and the procedures in § 60.2690. Opacity must be measured using EPA Reference Method 9 at 40 CFR part 60. Annual performance tests are not required if you use CEMS or continuous opacity monitoring systems to determine compliance.

(c) You must continuously monitor the operating parameters specified in § 60.2675 or established under § 60.2680 and as specified in § 60.2735. Operation above the established maximum or below the established minimum operating limits constitutes a deviation from the established operating limits. Three-hour block average values are used to determine compliance (except for baghouse leak detection system alarms) unless a different averaging period is established under § 60.2680 or, for energy recovery units, where the averaging time for each operating parameter is a 30-day rolling, calculated each hour as the average of the previous 720 operating hours over the previous 30 days of operation. Operation above the established maximum, below the established minimum, or outside the allowable range of the operating limits specified in paragraph (a) of this section constitutes a deviation from your operating limits established under this subpart, except during performance tests conducted to determine compliance with the emission and operating limits or to establish new operating limits. Operating limits are confirmed or reestablished during performance tests.

(d) You must burn only the same types of waste and fuels used to establish subcategory applicability (for ERUs) and operating limits during the performance test.

(e) For energy recovery units, incinerators, and small remote units, you must perform annual visual emissions test for ash handling.

(f) For energy recovery units, you must conduct an annual performance test for opacity using EPA Reference Method 9 at 40 CFR part 60 (except where particulate matter continuous monitoring system or continuous parameter monitoring systems are used) and the pollutants listed in table 7 of this subpart.

(g) For facilities using a CEMS to demonstrate compliance with the carbon monoxide emission limit, compliance with the carbon monoxide emission limit may be demonstrated by using the CEMS according to the following requirements:

(1) You must measure emissions according to § 60.13 to calculate 1-hour arithmetic averages, corrected to 7 percent oxygen. CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content. You must demonstrate initial compliance with the carbon monoxide emissions limit using a 30-day rolling average of the 1-hour arithmetic average emission concentrations, including CEMS data during startup and shutdown as defined in this subpart, calculated using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, appendix A–7.

(2) Operate the carbon monoxide continuous emissions monitoring system in accordance with the applicable requirements of performance specification 4A of appendix B and the quality assurance procedures of appendix F of this part.

(h) Coal and liquid/gas energy recovery units with annual average heat input rates greater than 250 MMBtu/hr may elect to demonstrate continuous compliance with the particulate matter emissions limit using a particulate matter CEMS according to the procedures in § 60.2730(n) instead of the continuous parameter monitoring system specified in § 60.2710(i). Coal and liquid/gas energy recovery units with annual average heat input rates less than 250 MMBtu/hr, incinerators, and small remote incinerators may also elect to demonstrate compliance using a particulate matter CEMS according to the procedures in § 60.2730(n) instead of particulate matter testing with EPA Method 5 at 40 CFR part 60, appendix A–3 and, if applicable, the continuous opacity monitoring requirements in paragraph (i) of this section.

(i) For energy recovery units with annual average heat input rates greater than or equal to 10 MMBTU/hour but less than 250 MMBtu/hr you must install, operate, certify and maintain a continuous opacity monitoring system (COMS) according to the procedures in § 60.2730.

(j) For waste-burning kilns, you must conduct an annual performance test for the pollutants (except mercury and particulate matter, and hydrogen chloride if no acid gas wet scrubber is used) listed in table 8 of this subpart. If you do not use an acid gas wet scrubber or dry scrubber, you must determine compliance with the hydrogen chloride emissions limit according to the requirements in paragraph (j)(1) of this section. You must determine compliance with the mercury emissions limit using a mercury CEMS according to paragraph (j)(2) of this section. You must determine compliance with particulate matter using CPMS:

(1) If you monitor compliance with the HCl emissions limit by operating an HCl CEMS, you must do so in accordance with Performance Specification 15 (PS 15) of appendix B to 40 CFR part 60, or, PS 18 of appendix B to 40 CFR part 60. You must operate, maintain, and quality assure a HCl CEMS installed and certified under PS 15 according to the quality assurance requirements in Procedure 1 of appendix F to 40 CFR part 60 except that the Relative Accuracy Test Audit requirements of Procedure 1 must be replaced with the validation requirements and criteria of sections 11.1.1 and 12.0 of PS 15. You must operate, maintain and quality assure a HCl CEMS installed and certified under PS 18 according to the quality assurance requirements in Procedure 6 of appendix F to 40 CFR part 60. For any performance specification that you use, you must use Method 321 of appendix A to 40 CFR part 63 as the reference test method for conducting relative accuracy testing. The span value and calibration requirements in paragraphs (j)(1)(i) and (ii) of this section apply to all HCl CEMS used under this subpart:

(i) You must use a measurement span value for any HCl CEMS of 0–10 ppmvw unless the monitor is installed on a kiln without an inline raw mill. Kilns without an inline raw mill may use a higher span value sufficient to quantify all expected emissions concentrations. The HCl CEMS data recorder output range must include the full range of expected HCl concentration values which would include those expected during "mill off" conditions. The corresponding data recorder range shall be documented in the site-specific monitoring plan and associated records; and

(ii) In order to quality assure data measured above the span value, you must use one of the three options in paragraphs (j)(1)(ii)(A) through (C) of this section:

(A) Include a second span that encompasses the HCl emission concentrations expected to be encountered during "mill off" conditions. This second span may be rounded to a multiple of 5 ppm of total HCl. The requirements of the appropriate HCl monitor performance specification shall be followed for this second span with the exception that a RATA with the mill off is not required;

(B) Quality assure any data above the span value by proving instrument linearity beyond the span value established in paragraph (j)(1)(i) of this section using the following procedure. Conduct a weekly "above span linearity" calibration challenge of the monitoring system using a reference gas with a certified value greater than your highest expected hourly concentration or greater than 75% of the highest measured hourly concentration. The "above span" reference gas must meet the requirements of the applicable performance specification and must be introduced to the measurement system at the probe. Record and report the results of this procedure as you would for a daily calibration. The "above span linearity" challenge is successful if the value measured by the HCl CEMS falls within 10 percent of the certified value of the reference gas. If the value measured by the HCl CEMS during the above span linearity challenge exceeds 10 percent of the certified value of the reference gas, the monitoring system must be evaluated and repaired and a new "above span linearity" challenge met before returning the HCl CEMS to service, or data above span from the HCl CEMS must be subject to the quality assurance procedures established in (j)(1)(ii)(D) of this section. In this manner values measured by the HCl CEMS during the above span linearity challenge exceeding +/−20 percent of the certified value of the reference gas must be normalized using equation 6;

(C) Quality assure any data above the span value established in paragraph (j)(1)(i) of this section using the following procedure. Any time two consecutive one-hour average measured concentration of HCl exceeds the span value you must, within 24 hours before or after, introduce a higher, "above span" HCl reference gas standard to the HCl CEMS. The "above span" reference gas must meet the requirements of the applicable performance specification and target a concentration level between 50 and 150 percent of the highest expected hourly concentration measured during the period of measurements above span, and must be introduced at the probe. While this target represents a desired concentration range that is not always achievable in practice, it is expected that the intent to meet this range is demonstrated by the value of the reference gas. Expected values may include above span calibrations done before or after the above-span measurement period. Record and report the results of this procedure as you would for a daily calibration. The "above span" calibration is successful if the value measured by the HCl CEMS is within 20 percent of the certified value of the reference gas. If the value measured by the HCl CEMS is not within 20 percent of the certified value of the reference gas, then you must normalize the stack gas values measured above span as described in paragraph (j)(1)(ii)(D) of this section. If the "above span" calibration is conducted during the period when measured emissions are above span and there is a failure to collect the one data point in an hour due to the calibration duration, then you must determine the emissions average for that missed hour as the average of hourly averages for the hour preceding the missed hour and the hour following the missed hour. In an hour where an "above span" calibration is being conducted and one or more data points are collected, the emissions average is represented by the average of all valid data points collected in that hour; and

(D) In the event that the "above span" calibration is not successful (*i.e.*, the HCl CEMS measured value is not within 20 percent of the certified value of the reference gas), then you must normalize the one-hour average stack gas values measured above the span during the 24-hour period preceding or following the "above span" calibration for reporting based on the HCl CEMS response to the reference gas as shown in equation 6:

$$\frac{\text{Certified reference gas value}}{\text{Measured value of reference gas}} = \text{Measured stack gas} = \text{Normalized stack gas result} \qquad \text{(Eq. 6)}$$

Only one "above span" calibration is needed per 24-hour period.

(2) Compliance with the mercury emissions limit must be determined using a mercury CEMS according to the following requirements:

(i) You must operate a CEMS in accordance with performance specification 12A at 40 CFR part 60, appendix B or a sorbent trap based integrated monitor in accordance with performance specification 12B at 40 CFR part 60, appendix B. The duration of the performance test must be a calendar month. For each calendar month in which the waste-burning kiln operates, hourly mercury concentration data and stack gas volumetric flow rate data must be obtained. You must demonstrate compliance with the mercury emissions limit using a 30-day rolling average of these 1-hour mercury concentrations, including CEMS data during startup and shutdown as defined in this subpart, calculated using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, appendix A–7 of this part. CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content;

(ii) Owners or operators using a mercury continuous emissions monitoring systems must install, operate, calibrate and maintain an instrument for continuously measuring and recording the mercury mass emissions rate to the atmosphere according to the requirements of performance specifications 6 and 12A at 40 CFR part 60, appendix B and quality assurance procedure 5 at 40 CFR part 60, appendix F; and

(iii) The owner or operator of a waste-burning kiln must demonstrate initial compliance by operating a mercury CEMS while the raw mill of the in-line kiln/raw mill is operating under normal conditions and including at least one period when the raw mill is off.

(k) If you use an air pollution control device to meet the emission limitations in this subpart, you must conduct an initial and annual inspection of the air pollution control device. The inspection must include, at a minimum, the following:

(1) Inspect air pollution control device(s) for proper operation; and

(2) Develop a site-specific monitoring plan according to the requirements in paragraph (l) of this section. This requirement also applies to you if you petition the EPA Administrator for alternative monitoring parameters under § 60.13(i).

(l) For each CMS required in this section, you must develop and submit to the EPA Administrator for approval a site-specific monitoring plan according to the requirements of this paragraph (l) that addresses paragraphs (l)(1)(i) through (vi) of this section:

(1) You must submit this site-specific monitoring plan at least 60 days before your initial performance evaluation of your continuous monitoring system:

(i) Installation of the continuous monitoring system sampling probe or other interface at a measurement location relative to each affected process unit such that the measurement is representative of control of the exhaust emissions (*e.g.,* on or downstream of the last control device);

(ii) Performance and equipment specifications for the sample interface, the pollutant concentration or parametric signal analyzer and the data collection and reduction systems;

(iii) Performance evaluation procedures and acceptance criteria (*e.g.,* calibrations);

(iv) Ongoing operation and maintenance procedures in accordance with the general requirements of § 60.11(d);

(v) Ongoing data quality assurance procedures in accordance with the general requirements of § 60.13; and

(vi) Ongoing recordkeeping and reporting procedures in accordance with the general requirements of § 60.7(b),(c), (c)(1), (c)(4), (d), (e), (f) and (g).

(2) You must conduct a performance evaluation of each continuous monitoring system in accordance with your site-specific monitoring plan.

(3) You must operate and maintain the continuous monitoring system in continuous operation according to the site-specific monitoring plan.

(m) If you have an operating limit that requires the use of a flow monitoring system, you must meet the requirements in paragraphs (l) and (m)(1) through (4) of this section:

(1) Install the flow sensor and other necessary equipment in a position that provides a representative flow;

(2) Use a flow sensor with a measurement sensitivity at full scale of no greater than 2 percent;

(3) Minimize the effects of swirling flow or abnormal velocity distributions due to upstream and downstream disturbances; and

(4) Conduct a flow monitoring system performance evaluation in accordance with your monitoring plan at the time of each performance test but no less frequently than annually.

(n) If you have an operating limit that requires the use of a pressure monitoring system, you must meet the requirements in paragraphs (l) and (n)(1) through (6) of this section:

(1) Install the pressure sensor(s) in a position that provides a representative measurement of the pressure (*e.g.,* PM scrubber pressure drop);

(2) Minimize or eliminate pulsating pressure, vibration, and internal and external corrosion;

(3) Use a pressure sensor with a minimum tolerance of 1.27 centimeters of water or a minimum tolerance of 1 percent of the pressure monitoring system operating range, whichever is less;

(4) Perform checks at the frequency outlined in your site-specific monitoring plan to ensure pressure measurements are not obstructed (*e.g.,* check for pressure tap plugging daily);

(5) Conduct a performance evaluation of the pressure monitoring system in accordance with your monitoring plan at the time of each performance test but no less frequently than annually; and

(6) If at any time the measured pressure exceeds the manufacturer's specified maximum operating pressure range, conduct a performance evaluation of the pressure monitoring system in accordance with your monitoring plan and confirm that the pressure monitoring system continues to meet the performance requirements in your monitoring plan. Alternatively, install and verify the operation of a new pressure sensor.

(o) If you have an operating limit that requires a pH monitoring system, you must meet the requirements in paragraphs (l) and (o)(1) through (4) of this section:

(1) Install the pH sensor in a position that provides a representative measurement of scrubber effluent pH;

(2) Ensure the sample is properly mixed and representative of the fluid to be measured;

(3) Conduct a performance evaluation of the pH monitoring system in accordance with your monitoring plan at least once each process operating day; and

(4) Conduct a performance evaluation (including a two-point calibration with one of the two buffer solutions having a pH within 1 of the pH of the operating limit) of the pH monitoring system in accordance with your monitoring plan at the time of each performance test but no less frequently than quarterly.

(p) If you have an operating limit that requires a secondary electric power monitoring system for an electrostatic precipitator, you must meet the requirements in paragraphs (l) and (p)(1) and (2) of this section:

(1) Install sensors to measure (secondary) voltage and current to the precipitator collection plates; and

(2) Conduct a performance evaluation of the electric power monitoring system in accordance with your monitoring plan at the time of each performance

test but no less frequently than annually.

(q) If you have an operating limit that requires the use of a monitoring system to measure sorbent injection rate (*e.g.*, weigh belt, weigh hopper, or hopper flow measurement device), you must meet the requirements in paragraphs (l) and (q)(1) and (2) of this section:

(1) Install the system in a position(s) that provides a representative measurement of the total sorbent injection rate; and

(2) Conduct a performance evaluation of the sorbent injection rate monitoring system in accordance with your monitoring plan at the time of each performance test but no less frequently than annually.

(r) If you elect to use a fabric filter bag leak detection system to comply with the requirements of this subpart, you must install, calibrate, maintain, and continuously operate a bag leak detection system as specified in paragraphs (l) and (r)(1) through (5) of this section:

(1) Install a bag leak detection sensor(s) in a position(s) that will be representative of the relative or absolute particulate matter loadings for each exhaust stack, roof vent, or compartment (*e.g.*, for a positive pressure fabric filter) of the fabric filter;

(2) Use a bag leak detection system certified by the manufacturer to be capable of detecting particulate matter emissions at concentrations of 10 milligrams per actual cubic meter or less;

(3) Conduct a performance evaluation of the bag leak detection system in accordance with your monitoring plan and consistent with the guidance provided in EPA–454/R–98–015 (incorporated by reference, *see* § 60.17);

(4) Use a bag leak detection system equipped with a device to continuously record the output signal from the sensor; and

(5) Use a bag leak detection system equipped with a system that will sound an alarm when an increase in relative particulate matter emissions over a preset level is detected. The alarm must be located where it is observed readily by plant operating personnel.

(s) For facilities using a CEMS to demonstrate compliance with the sulfur dioxide emission limit, compliance with the sulfur dioxide emission limit may be demonstrated by using the CEMS specified in § 60.2730 to measure sulfur dioxide. CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content. You must calculate a 30-day rolling average of the 1-hour arithmetic average emission concentrations, including CEMS data during startup and shutdown as defined in this subpart, using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, appendix A–7. The sulfur dioxide CEMS must be operated according to performance specification 2 in appendix B of this part and must follow the procedures and methods specified in paragraph (s) of this section. For sources that have actual inlet emissions less than 100 parts per million dry volume, the relative accuracy criterion for inlet sulfur dioxide CEMS should be no greater than 20 percent of the mean value of the reference method test data in terms of the units of the emission standard, or 5 parts per million dry volume absolute value of the mean difference between the reference method and the CEMS, whichever is greater:

(1) During each relative accuracy test run of the CEMS required by performance specification 2 in appendix B of this part, collect sulfur dioxide and oxygen (or carbon dioxide) data concurrently (or within a 30- to 60-minute period) with both the CEMS and the test methods specified in paragraphs (s)(1)(i) and (ii) of this section:

(i) For sulfur dioxide, EPA Reference Method 6 or 6C, or as an alternative ANSI/ASME PTC 19.10–1981 (incorporated by reference, see § 60.17) must be used; and

(ii) For oxygen (or carbon dioxide), EPA Reference Method 3A or 3B, or as an alternative ANSI/ASME PTC 19.10–1981 (incorporated by reference, see § 60.17), as applicable, must be used.

(2) The span value of the CEMS at the inlet to the sulfur dioxide control device must be 125 percent of the maximum estimated hourly potential sulfur dioxide emissions of the unit subject to this subpart. The span value of the CEMS at the outlet of the sulfur dioxide control device must be 50 percent of the maximum estimated hourly potential sulfur dioxide emissions of the unit subject to this subpart.

(3) Conduct accuracy determinations quarterly and calibration drift tests daily in accordance with procedure 1 in appendix F of this part.

(t) For facilities using a CEMS to demonstrate continuous compliance with the nitrogen oxides emission limit, compliance with the nitrogen oxides emission limit may be demonstrated by using the CEMS specified in § 60.2730 to measure nitrogen oxides. CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content. You must calculate a 30-day rolling average of the 1-hour arithmetic average emission concentration using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, appendix A–7. The nitrogen oxides CEMS must be operated according to performance specification 2 in appendix B of this part and must follow the procedures and methods specified in paragraphs (t)(1) through (4) of this section:

(1) During each relative accuracy test run of the CEMS required by performance specification 2 of appendix B of this part, collect nitrogen oxides and oxygen (or carbon dioxide) data concurrently (or within a 30- to 60-minute period) with both the CEMS and the test methods specified in paragraphs (t)(1)(i) and (ii) of this section:

(i) For nitrogen oxides, EPA Reference Method 7 or 7E at 40 CFR part 60, appendix A–4 must be used; and

(ii) For oxygen (or carbon dioxide), EPA Reference Method 3A or 3B, or as an alternative ANSI/ASME PTC 19.10–1981 (incorporated by reference, see § 60.17), as applicable, must be used.

(2) The span value of the CEMS must be 125 percent of the maximum estimated hourly potential nitrogen oxide emissions of unit.

(3) Conduct accuracy determinations quarterly and calibration drift tests daily in accordance with procedure 1 in appendix F of this part.

(4) The owner or operator of an affected facility may request that compliance with the nitrogen oxides emission limit be determined using carbon dioxide measurements corrected to an equivalent of 7 percent oxygen. If carbon dioxide is selected for use in diluent corrections, the relationship between oxygen and carbon dioxide levels must be established during the initial performance test according to the procedures and methods specified in paragraphs (t)(4)(i) through (iv) of this section. This relationship may be reestablished during performance compliance tests:

(i) The fuel factor equation in Method 3B must be used to determine the relationship between oxygen and carbon dioxide at a sampling location. Method 3A, 3B, or as an alternative ANSI/ASME PTC 19.10–1981 (incorporated by reference, see § 60.17), as applicable, must be used to determine the oxygen concentration at the same location as the carbon dioxide monitor;

(ii) Samples must be taken for at least 30 minutes in each hour;

(iii) Each sample must represent a 1-hour average; and

(iv) A minimum of 3 runs must be performed.

(u) For facilities using a continuous emissions monitoring system to demonstrate continuous compliance with any of the emission limits of this subpart, you must complete the following:

(1) Demonstrate compliance with the appropriate emission limit(s) using a 30-day rolling average of 1-hour arithmetic average emission concentrations, including CEMS data during startup and shutdown, as defined in this subpart, calculated using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, appendix A–7. CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content; and

(2) Operate all CEMS in accordance with the applicable procedures under appendices B and F of this part.

(v) Use of the bypass stack at any time is an emissions standards deviation for particulate matter, HCl, Pb, Cd, Hg, NO_X, SO_2, and dioxin/furans.

(w) For energy recovery units with a design heat input capacity of 100 MMBtu per hour or greater that do not use a carbon monoxide CEMS, you must install, operate, and maintain an oxygen analyzer system as defined in § 60.2875 according to the procedures in paragraphs (w)(1) through (4) of this section:

(1) The oxygen analyzer system must be installed by the initial performance test date specified in § 60.2675;

(2) You must operate the oxygen trim system within compliance with paragraph (w)(3) of this section at all times;

(3) You must maintain the oxygen level such that the 30-day rolling average that is established as the operating limit for oxygen is not below the lowest hourly average oxygen concentration measured during the most recent CO performance test; and

(4) You must calculate and record a 30-day rolling average oxygen concentration using equation 19–19 in section 12.4.1 of EPA Reference Method 19 of Appendix A–7 of this part.

(x) For energy recovery units with annual average heat input rates greater than or equal to 250 MMBtu/hour and waste-burning kilns, you must install, calibrate, maintain, and operate a PM CPMS and record the output of the system as specified in paragraphs (x)(1) through (8) of this section. For other energy recovery units, you may elect to use PM CPMS operated in accordance with this section. PM CPMS are suitable in lieu of using other CMS for monitoring PM compliance (*e.g.*, bag leak detectors, ESP secondary power, PM scrubber pressure):

(1) Install, calibrate, operate, and maintain your PM CPMS according to the procedures in your approved site-specific monitoring plan developed in accordance with paragraphs (l) and (x)(1)(i) through (iii) of this section:

(i) The operating principle of the PM CPMS must be based on in-stack or extractive light scatter, light scintillation, beta attenuation, or mass accumulation of the exhaust gas or representative sample. The reportable measurement output from the PM CPMS must be expressed as milliamps or the digital signal equivalent;

(ii) The PM CPMS must have a cycle time (*i.e.*, period required to complete sampling, measurement, and reporting for each measurement) no longer than 60 minutes; and

(iii) The PM CPMS must be capable of detecting and responding to particulate matter concentrations increments no greater than 0.5 mg/actual cubic meter.

(2) During the initial performance test or any such subsequent performance test that demonstrates compliance with the PM limit, you must adjust the site-specific operating limit in accordance with the results of the performance test according to the procedures specified in § 60.2675.

(3) Collect PM CPMS hourly average output data for all energy recovery unit or waste-burning kiln operating hours. Express the PM CPMS output as milliamps or the digital signal equivalent.

(4) Calculate the arithmetic 30-day rolling average of all of the hourly average PM CPMS output collected during all energy recovery unit or waste-burning kiln operating hours data (milliamps or their digital equivalent).

(5) You must collect data using the PM CPMS at all times the energy recovery unit or waste-burning kiln is operating and at the intervals specified in paragraph (x)(1)(ii) of this section, except for periods of monitoring system malfunctions, repairs associated with monitoring system malfunctions, required monitoring system quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments), and any scheduled maintenance as defined in your site-specific monitoring plan.

(6) You must use all the data collected during all energy recovery unit or waste-burning kiln operating hours in assessing the compliance with your operating limit except:

(i) Any data collected during monitoring system malfunctions, repairs associated with monitoring system malfunctions, or required monitoring system quality assurance or quality control activities conducted during monitoring system malfunctions are not used in calculations (report any such periods in your annual deviation report);

(ii) Any data collected during periods when the monitoring system is out of control as specified in your site-specific monitoring plan, repairs associated with periods when the monitoring system is out of control, or required monitoring system quality assurance or quality control activities conducted during out-of-control periods are not used in calculations (report emissions or operating levels and report any such periods in your annual deviation report);

(iii) Any PM CPMS data recorded during periods of CEMS data during startup and shutdown, as defined in this subpart.

(7) You must record and make available upon request results of PM CPMS system performance audits, as well as the dates and duration of periods from when the PM CPMS is out of control until completion of the corrective actions necessary to return the PM CPMS to operation consistent with your site-specific monitoring plan.

(8) For any deviation of the 30-day rolling average PM CPMS average value from the established operating parameter limit, you must:

(i) Within 48 hours of the deviation, visually inspect the air pollution control device;

(ii) If inspection of the air pollution control device identifies the cause of the deviation, take corrective action as soon as possible and return the PM CPMS measurement to within the established value;

(iii) Within 30 days of the deviation or at the time of the annual compliance test, whichever comes first, conduct a PM emissions compliance test to determine compliance with the PM emissions limit and to verify. Within 45 days of the deviation, you must re-establish the CPMS operating limit. You are not required to conduct additional testing for any deviations that occur between the time of the original deviation and the PM emissions compliance test required under paragraph (x) of this section; and

(iv) PM CPMS deviations leading to more than four required performance tests in a 12-month process operating period (rolling monthly) constitute a violation of this subpart.

(y) When there is an alkali bypass and/or an in-line coal mill that exhaust emissions through a separate stack(s), the combined emissions are subject to the emission limits applicable to waste-burning kilns. To determine the kiln-specific emission limit for demonstrating compliance, you must:

(1) Calculate a kiln-specific emission limit using equation 7:

$$C_{ks} = ((\text{Emission limit} \times (Q_{ab}+Q_{cm}+Q_{ks})) - (Q_{ab} \times C_{ab}) - (Q_{cm} \times C_{cm}))/Q_{ks} \qquad \text{(Eq. 7)}$$

Where:

C_{ks} = Kiln stack concentration (ppmvd, mg/dscm, ng/dscm, depending on pollutant. Each corrected to 7% O_2.)
Q_{ab} = Alkali bypass flow rate (volume/hr)
C_{ab} = Alkali bypass concentration (ppmvd, mg/dscm, ng/dscm, depending on pollutant. Each corrected to 7% O_2.)
Q_{cm} = In-line coal mill flow rate (volume/hr)
C_{cm} = In-line coal mill concentration (ppmvd, mg/dscm, ng/dscm, depending on pollutant. Each corrected to 7% O_2.)
Q_{ks} = Kiln stack flow rate (volume/hr)

(2) Particulate matter concentration must be measured downstream of the in-line coal mill. All other pollutant concentrations must be measured either upstream or downstream of the in-line coal mill.

(3) For purposes of determining the combined emissions from kilns equipped with an alkali bypass or that exhaust kiln gases to a coal mill that exhausts through a separate stack, instead of installing a CEMS or PM CPMS on the alkali bypass stack or in-line coal mill stack, the results of the initial and subsequent performance test can be used to demonstrate compliance with the relevant emissions limit. A performance test must be conducted on an annual basis (between 11 and 13 calendar months following the previous performance test).

§ 60.2715 By what date must I conduct the annual performance test?

You must conduct annual performance tests between 11 and 13 months of the previous performance test.

§ 60.2716 By what date must I conduct the annual air pollution control device inspection?

On an annual basis (no more than 12 months following the previous annual air pollution control device inspection), you must complete the air pollution control device inspection as described in § 60.2706.

§ 60.2720 May I conduct performance testing less often?

(a) You must conduct annual performance tests according to the schedule specified in § 60.2715, with the following exceptions:

(1) You may conduct a repeat performance test at any time to establish new values for the operating limits to apply from that point forward, as specified in § 60.2725. The Administrator may request a repeat performance test at any time;

(2) You must repeat the performance test within 60 days of a process change, as defined in § 60.2875; and

(3) If the initial or any subsequent performance test for any pollutant in table 2 or tables 6 through 9 of this subpart, as applicable, demonstrates that the emission level for the pollutant is no greater than the emission level specified in paragraph (a)(3)(i) or (a)(3)(ii) of this section, as applicable, and you are not required to conduct a performance test for the pollutant in response to a request by the Administrator in paragraph (a)(1) of this section or a process change in paragraph (a)(2) of this section, you may elect to skip conducting a performance test for the pollutant for the next 2 years. You must conduct a performance test for the pollutant during the third year and no more than 37 months following the previous performance test for the pollutant. For cadmium and lead, both cadmium and lead must be emitted at emission levels no greater than their respective emission levels specified in paragraph (a)(3)(i) of this section for you to qualify for less frequent testing under paragraph (a) of this section:

(i) For particulate matter, hydrogen chloride, mercury, carbon monoxide, nitrogen oxides, sulfur dioxide, cadmium, lead, and dioxins/furans, the emission level equal to 75 percent of the applicable emission limit in table 2 or tables 6 through 9 of this subpart, as applicable, to this subpart; and

(ii) For fugitive emissions, visible emissions (of combustion ash from the ash conveying system) for 2 percent of the time during each of the three 1-hour observation periods.

(4) If you are conducting less frequent testing for a pollutant as provided in paragraph (a)(3) of this section and a subsequent performance test for the pollutant indicates that your CISWI unit does not meet the emission level specified in paragraph (a)(3)(i) or (a)(3)(ii) of this section, as applicable, you must conduct annual performance tests for the pollutant according to the schedule specified in paragraph (a) of this section until you qualify for less frequent testing for the pollutant as specified in paragraph (a)(3) of this section.

(b) [Reserved]

§ 60.2725 May I conduct a repeat performance test to establish new operating limits?

(a) Yes. You may conduct a repeat performance test at any time to establish new values for the operating limits. The Administrator may request a repeat performance test at any time.

(b) You must repeat the performance test if your feed stream is different than the feed streams used during any performance test used to demonstrate compliance.

Model Rule—Monitoring

§ 60.2730 What monitoring equipment must I install and what parameters must I monitor?

(a) If you are using a wet scrubber to comply with the emission limitation under § 60.2670, you must install, calibrate (to manufacturers' specifications), maintain, and operate devices (or establish methods) for monitoring the value of the operating parameters used to determine compliance with the operating limits listed in table 3 of this subpart. These devices (or methods) must measure and record the values for these operating parameters at the frequencies indicated in table 3 of this subpart at all times except as specified in § 60.2735(a).

(b) If you use a fabric filter to comply with the requirements of this subpart and you do not use a PM CPMS for monitoring PM compliance, you must install, calibrate, maintain, and continuously operate a bag leak detection system as specified in paragraphs (b)(1) through (8) of this section:

(1) You must install and operate a bag leak detection system for each exhaust stack of the fabric filter;

(2) Each bag leak detection system must be installed, operated, calibrated, and maintained in a manner consistent with the manufacturer's written specifications and recommendations;

(3) The bag leak detection system must be certified by the manufacturer to be capable of detecting particulate matter emissions at concentrations of 10 milligrams per actual cubic meter or less;

(4) The bag leak detection system sensor must provide output of relative or absolute particulate matter loadings;

(5) The bag leak detection system must be equipped with a device to continuously record the output signal from the sensor;

(6) The bag leak detection system must be equipped with an alarm system that will alert automatically an operator when an increase in relative particulate matter emission over a preset level is detected. The alarm must be located where it is observed easily by plant operating personnel;

(7) For positive pressure fabric filter systems, a bag leak detection system must be installed in each baghouse compartment or cell. For negative pressure or induced air fabric filters, the bag leak detector must be installed downstream of the fabric filter; and

(8) Where multiple detectors are required, the system's instrumentation and alarm may be shared among detectors.

(c) If you are using something other than a wet scrubber, activated carbon, selective non-catalytic reduction, an electrostatic precipitator, or a dry scrubber to comply with the emission limitations under § 60.2670, you must install, calibrate (to the manufacturers' specifications), maintain, and operate the equipment necessary to monitor compliance with the site-specific operating limits established using the procedures in § 60.2680.

(d) If you use activated carbon injection to comply with the emission limitations in this subpart, you must measure the minimum sorbent flow rate once per hour.

(e) If you use selective noncatalytic reduction to comply with the emission limitations, you must complete the following:

(1) Following the date on which the initial performance test is completed or is required to be completed under § 60.2690, whichever date comes first, ensure that the affected facility does not operate above the maximum charge rate, or below the minimum secondary chamber temperature (if applicable to your CISWI unit) or the minimum reagent flow rate measured as 3-hour block averages at all times; and

(2) Operation of the affected facility above the maximum charge rate, below the minimum secondary chamber temperature and below the minimum reagent flow rate simultaneously constitute a violation of the nitrogen oxides emissions limit.

(f) If you use an electrostatic precipitator to comply with the emission limits of this subpart and you do not use a PM CPMS for monitoring PM compliance, you must monitor the secondary power to the electrostatic precipitator collection plates and maintain the 3-hour block averages at or above the operating limits established during the mercury or particulate matter performance test.

(g) For waste-burning kilns not equipped with a wet scrubber or dry scrubber, in place of hydrogen chloride testing with EPA Method 321 at 40 CFR part 63, appendix A, an owner or operator must install, calibrate, maintain, and operate a CEMS for monitoring hydrogen chloride emissions, as specified in § 60.2710(j), discharged to the atmosphere and record the output of the system. To demonstrate continuous compliance with the hydrogen chloride emissions limit for units other than waste-burning kilns not equipped with a wet scrubber or dry scrubber, a facility may substitute use of a hydrogen chloride CEMS for conducting the hydrogen chloride annual performance test, monitoring the minimum hydrogen chloride sorbent flow rate, monitoring the minimum scrubber liquor pH.

(h) To demonstrate continuous compliance with the particulate matter emissions limit, a facility may substitute use of either a particulate matter CEMS or a particulate matter CPMS for conducting the particulate matter annual performance test and other CMS monitoring for PM compliance (*e.g.,* bag leak detectors, ESP secondary power, PM scrubber pressure).

(i) To demonstrate continuous compliance with the dioxin/furan emissions limit, a facility may substitute use of a continuous automated sampling system for the dioxin/furan annual performance test. You must record the output of the system and analyze the sample according to EPA Method 23 at 40 CFR part 60, appendix A–7. This option to use a continuous automated sampling system takes effect on the date a final performance specification applicable to dioxin/furan from continuous monitors is published in the **Federal Register**. The owner or operator who elects to continuously sample dioxin/furan emissions instead of sampling and testing using EPA Method 23 at 40 CFR part 60, appendix A–7 must install, calibrate, maintain and operate a continuous automated sampling system and must comply with the requirements specified in § 60.58b(p) and (q). A facility may substitute continuous dioxin/furan monitoring for the minimum sorbent flow rate, if activated carbon sorbent injection is used solely for compliance with the dioxin/furan emission limit.

(j) To demonstrate continuous compliance with the mercury emissions limit, a facility may substitute use of a continuous automated sampling system for the mercury annual performance test. You must record the output of the system and analyze the sample at set intervals using any suitable determinative technique that can meet performance specification 12B criteria. This option to use a continuous automated sampling system takes effect on the date a final performance specification applicable to mercury from monitors is published in the **Federal Register**. The owner or operator who elects to continuously sample mercury emissions instead of sampling and testing using EPA Method 29 or 30B at 40 CFR part 60, appendix A–8, ASTM D6784–02 (Reapproved 2008) (incorporated by reference, see § 60.17), or an approved alternative method for measuring mercury emissions, must install, calibrate, maintain and operate a continuous automated sampling system and must comply with the requirements specified in § 60.58b(p) and (q). A facility may substitute continuous mercury monitoring for the minimum sorbent flow rate, if activated carbon sorbent injection is used solely for compliance with the mercury emission limit. Waste-burning kilns must install, calibrate, maintain, and operate a mercury CEMS as specified in § 60.2710(j).

(k) To demonstrate continuous compliance with the nitrogen oxides emissions limit, a facility may substitute use of a CEMS for the nitrogen oxides annual performance test to demonstrate compliance with the nitrogen oxides emissions limits and monitoring the charge rate, secondary chamber temperature and reagent flow for selective noncatalytic reduction, if applicable:

(1) Install, calibrate, maintain and operate a CEMS for measuring nitrogen oxides emissions discharged to the atmosphere and record the output of the system. The requirements under performance specification 2 of appendix B of this part, the quality assurance procedure 1 of appendix F of this part and the procedures under § 60.13 must be followed for installation, evaluation and operation of the CEMS; and

(2) Following the date that the initial performance test for nitrogen oxides is completed or is required to be completed under § 60.2690, compliance with the emission limit for nitrogen oxides required under § 60.52b(d) must be determined based on the 30-day rolling average of the hourly emission concentrations using CEMS outlet data. The 1-hour arithmetic averages must be expressed in parts per million by volume corrected to 7 percent oxygen (dry basis) and used to calculate the 30-day rolling average concentrations.

CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content. The 1-hour arithmetic averages must be calculated using the data points required under § 60.13(e)(2).

(l) To demonstrate continuous compliance with the sulfur dioxide emissions limit, a facility may substitute use of a continuous automated sampling system for the sulfur dioxide annual performance test to demonstrate compliance with the sulfur dioxide emissions limits:

(1) Install, calibrate, maintain and operate a CEMS for measuring sulfur dioxide emissions discharged to the atmosphere and record the output of the system. The requirements under performance specification 2 of appendix B of this part, the quality assurance requirements of procedure 1 of appendix F of this part and the procedures under § 60.13 must be followed for installation, evaluation and operation of the CEMS; and

(2) Following the date that the initial performance test for sulfur dioxide is completed or is required to be completed under § 60.2690, compliance with the sulfur dioxide emission limit may be determined based on the 30-day rolling average of the hourly arithmetic average emission concentrations using CEMS outlet data. The 1-hour arithmetic averages must be expressed in parts per million corrected to 7 percent oxygen (dry basis) and used to calculate the 30-day rolling average emission concentrations. CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content. The 1-hour arithmetic averages must be calculated using the data points required under § 60.13(e)(2).

(m) For energy recovery units over 10 MMBtu/hr but less than 250 MMBtu/hr annual average heat input rates that do not use a wet scrubber, fabric filter with bag leak detection system, or particulate matter CEMS, you must install, operate, certify and maintain a continuous opacity monitoring system according to the procedures in paragraphs (m)(1) through (5) of this section by the compliance date specified in § 60.2670. Energy recovery units that use a particulate matter CEMS to demonstrate initial and continuing compliance according to the procedures in § 60.2730(n) are not required to install a continuous opacity monitoring system and must perform the annual performance tests for opacity consistent with § 60.2710(f):

(1) Install, operate and maintain each continuous opacity monitoring system according to performance specification 1 at 40 CFR part 60, appendix B;

(2) Conduct a performance evaluation of each continuous opacity monitoring system according to the requirements in § 60.13 and according to performance specification 1 at 40 CFR part 60, appendix B;

(3) As specified in § 60.13(e)(1), each continuous opacity monitoring system must complete a minimum of one cycle of sampling and analyzing for each successive 10-second period and one cycle of data recording for each successive 6-minute period;

(4) Reduce the continuous opacity monitoring system data as specified in § 60.13(h)(1); and

(5) Determine and record all the 6-minute averages (and 1-hour block averages as applicable) collected.

(n) For coal and liquid/gas energy recovery units, incinerators, and small remote incinerators, an owner or operator may elect to install, calibrate, maintain and operate a CEMS for monitoring particulate matter emissions discharged to the atmosphere and record the output of the system. The owner or operator of an affected facility who continuously monitors particulate matter emissions instead of conducting performance testing using EPA Method 5 at 40 CFR part 60, appendix A–3 or, as applicable, monitor with a particulate matter CPMS according to paragraph (r) of this section, must install, calibrate, maintain and operate a CEMS and must comply with the requirements specified in paragraphs (n)(1) through (13) of this section:

(1) Notify the Administrator 1 month before starting use of the system;

(2) Notify the Administrator 1 month before stopping use of the system;

(3) The monitor must be installed, evaluated and operated in accordance with the requirements of performance specification 11 of appendix B of this part and quality assurance requirements of procedure 2 of appendix F of this part and § 60.13;

(4) The initial performance evaluation must be completed no later than 180 days after the final compliance date for meeting the amended emission limitations, as specified under § 60.2690 or within 180 days of notification to the Administrator of use of the continuous monitoring system if the owner or operator was previously determining compliance by Method 5 at 40 CFR part 60, appendix A–3 performance tests, whichever is later;

(5) The owner or operator of an affected facility may request that compliance with the particulate matter emission limit be determined using carbon dioxide measurements corrected to an equivalent of 7 percent oxygen. The relationship between oxygen and carbon dioxide levels for the affected facility must be established according to the procedures and methods specified in § 60.2710(t)(4)(i) through (iv);

(6) The owner or operator of an affected facility must conduct an initial performance test for particulate matter emissions as required under § 60.2690. Compliance with the particulate matter emission limit, if PM CEMS are elected for demonstrating compliance, must be determined by using the CEMS specified in paragraph (n) of this section to measure particulate matter. You must calculate a 30-day rolling average of 1-hour arithmetic average emission concentrations, including CEMS data during startup and shutdown, as defined in this subpart, using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, appendix A–7 of this part;

(7) Compliance with the particulate matter emission limit must be determined based on the 30-day rolling average calculated using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, Appendix A–7 of the part from the 1-hour arithmetic average of the CEMS outlet data.

(8) At a minimum, valid continuous monitoring system hourly averages must be obtained as specified § 60.2735;

(9) The 1-hour arithmetic averages required under paragraph (n)(7) of this section must be expressed in milligrams per dry standard cubic meter corrected to 7 percent oxygen (or carbon dioxide) (dry basis) and must be used to calculate the 30-day rolling average emission concentrations. CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content. The 1-hour arithmetic averages must be calculated using the data points required under § 60.13(e)(2);

(10) All valid CEMS data must be used in calculating average emission concentrations even if the minimum CEMS data requirements of paragraph (n)(8) of this section are not met;

(11) The CEMS must be operated according to performance specification 11 in appendix B of this part;

(12) During each relative accuracy test run of the CEMS required by performance specification 11 in appendix B of this part, particulate matter and oxygen (or carbon dioxide) data must be collected concurrently (or within a 30-to 60-minute period) by both the CEMS and the following test methods:

(i) For particulate matter, EPA Reference Method 5 at 40 CFR part 60, appendix A–3 must be used; and

(ii) For oxygen (or carbon dioxide), EPA Reference Method 3A or 3B at 40 CFR part 60, appendix A–2, as applicable, must be used; and

(13) Quarterly accuracy determinations and daily calibration drift tests must be performed in accordance with procedure 2 in appendix F of this part.

(o) To demonstrate continuous compliance with the carbon monoxide emissions limit, a facility may substitute use of a continuous automated sampling system for the carbon monoxide annual performance test to demonstrate compliance with the carbon monoxide emissions limits:

(1) Install, calibrate, maintain, and operate a CEMS for measuring carbon monoxide emissions discharged to the atmosphere and record the output of the system. The requirements under performance specification 4B of appendix B of this part, the quality assurance procedure 1 of appendix F of this part and the procedures under § 60.13 must be followed for installation, evaluation, and operation of the CEMS; and

(2) Following the date that the initial performance test for carbon monoxide is completed or is required to be completed under § 60.2690, compliance with the carbon monoxide emission limit may be determined based on the 30-day rolling average of the hourly arithmetic average emission concentrations, including CEMS data during startup and shutdown as defined in this subpart, using CEMS outlet data. Except for CEMS data during startup and shutdown, as defined in this subpart, the 1-hour arithmetic averages must be expressed in parts per million corrected to 7 percent oxygen (dry basis) and used to calculate the 30-day rolling average emission concentrations. CEMS data collected during startup or shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content. The 1-hour arithmetic averages must be calculated using the data points required under § 60.13(e)(2).

(p) The owner/operator of an affected source with a bypass stack shall install, calibrate (to manufacturers' specifications), maintain and operate a device or method for measuring the use of the bypass stack including date, time and duration.

(q) For energy recovery units with a heat input capacity of 100 MMBtu per hour or greater that do not use a carbon monoxide CEMS, you must install, operate and maintain the continuous oxygen monitoring system as defined in § 60.2875 according to the procedures in paragraphs (q)(1) through (4) of this section:

(1) The oxygen analyzer system must be installed by the initial performance test date specified in § 60.2675;

(2) You must operate the oxygen trim system within compliance with paragraph (q)(3) of this section at all times;

(3) You must maintain the oxygen level such that the 30-day rolling average that is established as the operating limit for oxygen according to paragraph (q)(4) of this section is not below the lowest hourly average oxygen concentration measured during the most recent CO performance test; and

(4) You must calculate and record a 30-day rolling average oxygen concentration using equation 19–19 in section 12.4.1 of EPA Reference Method 19 of Appendix A–7 of this part.

(r) For energy recovery units with annual average heat input rates greater than or equal to 250 MMBtu/hour and waste-burning kilns, you must install, calibrate, maintain, and operate a PM CPMS and record the output of the system as specified in paragraphs (r)(1) through (8) of this section. For other energy recovery units, you may elect to use PM CPMS operated in accordance with this section. PM CPMS are suitable in lieu of using other CMS for monitoring PM compliance (*e.g.,* bag leak detectors, ESP secondary power, PM scrubber pressure):

(1) Install, calibrate, operate, and maintain your PM CPMS according to the procedures in your approved site-specific monitoring plan developed in accordance with § 60.2710(l) and (r)(1)(i) through (iii) of this section:

(i) The operating principle of the PM CPMS must be based on in-stack or extractive light scatter, light scintillation, beta attenuation, or mass accumulation of the exhaust gas or representative sample. The reportable measurement output from the PM CPMS must be expressed as milliamps or the digital signal equivalent;

(ii) The PM CPMS must have a cycle time (*i.e.,* period required to complete sampling, measurement, and reporting for each measurement) no longer than 60 minutes; and

(iii) The PM CPMS must be capable of detecting and responding to particulate matter concentrations increments no greater than 0.5 mg/actual cubic meter.

(2) During the initial performance test or any such subsequent performance test that demonstrates compliance with the PM limit, you must adjust the site-specific operating limit in accordance with the results of the performance test according to the procedures specified in § 60.2675.

(3) Collect PM CPMS hourly average output data for all energy recovery unit or waste-burning kiln operating hours. Express the PM CPMS output as milliamps or the digital signal equivalent.

(4) Calculate the arithmetic 30-day rolling average of all of the hourly average PM CPMS output collected during all energy recovery unit or waste-burning kiln operating hours data (milliamps or digital bits).

(5) You must collect data using the PM CPMS at all times the energy recovery unit or waste-burning kiln is operating and at the intervals specified in paragraph (r)(1)(ii) of this section, except for periods of monitoring system malfunctions, repairs associated with monitoring system malfunctions, required monitoring system quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments), and any scheduled maintenance as defined in your site-specific monitoring plan.

(6) You must use all the data collected during all energy recovery unit or waste-burning kiln operating hours in assessing the compliance with your operating limit except:

(i) Any data collected during monitoring system malfunctions, repairs associated with monitoring system malfunctions, or required monitoring system quality assurance or quality control activities conducted during monitoring system malfunctions are not used in calculations (report any such periods in your annual deviation report);

(ii) Any data collected during periods when the monitoring system is out of control as specified in your site-specific monitoring plan, repairs associated with periods when the monitoring system is out of control, or required monitoring system quality assurance or quality control activities conducted during out-of-control periods are not used in calculations (report emissions or operating levels and report any such periods in your annual deviation report); and

(iii) Any PM CPMS data recorded during periods of CEMS data during startup and shutdown, as defined in this subpart.

(7) You must record and make available upon request results of PM CPMS system performance audits, as well as the dates and duration of periods from when the PM CPMS is out of control until completion of the corrective actions necessary to return

the PM CPMS to operation consistent with your site-specific monitoring plan.

(8) For any deviation of the 30-day rolling average PM CPMS average value from the established operating parameter limit, you must:

(i) Within 48 hours of the deviation, visually inspect the air pollution control device;

(ii) If inspection of the air pollution control device identifies the cause of the deviation, take corrective action as soon as possible and return the PM CPMS measurement to within the established value;

(iii) Within 30 days of the deviation or at the time of the annual compliance test, whichever comes first, conduct a PM emissions compliance test to determine compliance with the PM emissions limit and to verify the operation of the emissions control device(s). Within 45 days of the deviation, you must re-establish the CPMS operating limit. You are not required to conduct additional testing for any deviations that occur between the time of the original deviation and the PM emissions compliance test required under this paragraph; and

(iv) PM CPMS deviations leading to more than four required performance tests in a 12-month process operating period (rolling monthly) constitute a violation of this subpart.

(s) If you use a dry scrubber to comply with the emission limits of this subpart, you must monitor the injection rate of each sorbent and maintain the 3-hour block averages at or above the operating limits established during the hydrogen chloride performance test.

§ 60.2735 Is there a minimum amount of monitoring data I must obtain?

For each continuous monitoring system required or optionally allowed under § 60.2730, you must monitor and collect data according to this section:

(a) You must operate the monitoring system and collect data at all required intervals at all times compliance is required except for periods of monitoring system malfunctions or out-of-control periods, repairs associated with monitoring system malfunctions or out-of-control periods (as specified in § 60.2770(o)), and required monitoring system quality assurance or quality control activities including, as applicable, calibration checks and required zero and span adjustments. A monitoring system malfunction is any sudden, infrequent, not reasonably preventable failure of the monitoring system to provide valid data. Monitoring system failures that are caused in part by poor maintenance or careless operation are not malfunctions. You are required to effect monitoring system repairs in response to monitoring system malfunctions or out-of-control periods and to return the monitoring system to operation as expeditiously as practicable.

(b) You may not use data recorded during the monitoring system malfunctions, repairs associated with monitoring system malfunctions or out-of control periods, or required monitoring system quality assurance or control activities in calculations used to report emissions or operating levels. You must use all the data collected during all other periods, including data normalized for above scale readings, in assessing the operation of the control device and associated control system.

(c) Except for periods of monitoring system malfunctions or out-of-control periods, repairs associated with monitoring system malfunctions or out-of-control periods, and required monitoring system quality assurance or quality control activities including, as applicable, calibration checks and required zero and span adjustments, failure to collect required data is a deviation of the monitoring requirements.

Model Rule—Recordkeeping and Reporting

§ 60.2740 What records must I keep?

You must maintain the items (as applicable) as specified in paragraphs (a), (b), and (e) through (w) of this section for a period of at least 5 years:

(a) Calendar date of each record;

(b) Records of the data described in paragraphs (b)(1) through (6) of this section:

(1) The CISWI unit charge dates, times, weights, and hourly charge rates;

(2) Liquor flow rate to the wet scrubber inlet every 15 minutes of operation, as applicable;

(3) Pressure drop across the wet scrubber system every 15 minutes of operation or amperage to the wet scrubber every 15 minutes of operation, as applicable;

(4) Liquor pH as introduced to the wet scrubber every 15 minutes of operation, as applicable;

(5) For affected CISWI units that establish operating limits for controls other than wet scrubbers under § 60.2675(d) through (g) or § 60.2680, you must maintain data collected for all operating parameters used to determine compliance with the operating limits. For energy recovery units using activated carbon injection or a dry scrubber, you must also maintain records of the load fraction and corresponding sorbent injection rate records; and

(6) If a fabric filter is used to comply with the emission limitations, you must record the date, time, and duration of each alarm and the time corrective action was initiated and completed, and a brief description of the cause of the alarm and the corrective action taken. You must also record the percent of operating time during each 6-month period that the alarm sounds, calculated as specified in § 60.2675(c).

(c)–(d) [Reserved]

(e) Identification of calendar dates and times for which data show a deviation from the operating limits in table 3 of this subpart or a deviation from other operating limits established under § 60.2675(d) through (g) or § 60.2680 with a description of the deviations, reasons for such deviations, and a description of corrective actions taken.

(f) The results of the initial, annual, and any subsequent performance tests conducted to determine compliance with the emission limits and/or to establish operating limits, as applicable. Retain a copy of the complete test report including calculations.

(g) Records showing the names of CISWI unit operators who have completed review of the information in § 60.2660(a) as required by § 60.2660(b), including the date of the initial review and all subsequent annual reviews.

(h) Records showing the names of the CISWI operators who have completed the operator training requirements under § 60.2635, met the criteria for qualification under § 60.2645, and maintained or renewed their qualification under § 60.2650 or § 60.2655. Records must include documentation of training, the dates of the initial and refresher training, and the dates of their qualification and all subsequent renewals of such qualifications.

(i) For each qualified operator, the phone and/or pager number at which they can be reached during operating hours.

(j) Records of calibration of any monitoring devices as required under § 60.2730.

(k) Equipment vendor specifications and related operation and maintenance requirements for the incinerator, emission controls, and monitoring equipment.

(l) The information listed in § 60.2660(a).

(m) On a daily basis, keep a log of the quantity of waste burned and the types of waste burned (always required).

(n) Maintain records of the annual air pollution control device inspections that are required for each CISWI unit subject to the emissions limits in table

2 of this subpart or tables 6 through 9 of this subpart, any required maintenance and any repairs not completed within 10 days of an inspection or the timeframe established by the state regulatory agency.

(o) For continuously monitored pollutants or parameters, you must document and keep a record of the following parameters measured using continuous monitoring systems:

(1) All 6-minute average levels of opacity;

(2) All 1-hour average concentrations of sulfur dioxide emissions. You must indicate which data are CEMS data during startup and shutdown;

(3) All 1-hour average concentrations of nitrogen oxides emissions. You must indicate which data are CEMS data during startup and shutdown;

(4) All 1-hour average concentrations of carbon monoxide emissions. You must indicate which data are CEMS data during startup and shutdown;

(5) All 1-hour average concentrations of particulate matter emissions. You must indicate which data are CEMS data during startup and shutdown;

(6) All 1-hour average concentrations of mercury emissions. You must indicate which data are CEMS data during startup and shutdown;

(7) All 1-hour average concentrations of hydrogen chloride emissions. You must indicate which data are CEMS data during startup and shutdown;

(8) All 1-hour average percent oxygen concentrations; and

(9) All 1-hour average PM CPMS readings or particulate matter CEMS outputs.

(p) Records indicating use of the bypass stack, including dates, times and durations.

(q) If you choose to stack test less frequently than annually, consistent with § 60.2720(a) through (c), you must keep annual records that document that your emissions in the previous stack test(s) were less than 75 percent of the applicable emission limit and document that there was no change in source operations including fuel composition and operation of air pollution control equipment that would cause emissions of the relevant pollutant to increase within the past year.

(r) Records of the occurrence and duration of each malfunction of operation (*i.e.*, process equipment) or the air pollution control and monitoring equipment.

(s) Records of all required maintenance performed on the air pollution control and monitoring equipment.

(t) Records of actions taken during periods of malfunction to minimize emissions in accordance with § 60.11(d), including corrective actions to restore malfunctioning process and air pollution control and monitoring equipment to its normal or usual manner of operation.

(u) For operating units that combust non-hazardous secondary materials that have been determined not to be solid waste pursuant to § 241.3(b)(1) of this chapter, you must keep a record which documents how the secondary material meets each of the legitimacy criteria under § 241.3(d)(1). If you combust a fuel that has been processed from a discarded non-hazardous secondary material pursuant to § 241.3(b)(4), you must keep records as to how the operations that produced the fuel satisfies the definition of processing in § 241.2 and each of the legitimacy criteria in § 241.3(d)(1) of this chapter. If the fuel received a non-waste determination pursuant to the petition process submitted under § 241.3(c), you must keep a record that documents how the fuel satisfies the requirements of the petition process. For operating units that combust non-hazardous secondary materials as fuel per § 241.4, you must keep records documenting that the material is a listed non-waste under § 241.4(a).

(v) Records of the criteria used to establish that the unit qualifies as a small power production facility under section 3(17)(C) of the Federal Power Act (16 U.S.C. 796(17)(C)) and that the waste material the unit is proposed to burn is homogeneous.

(w) Records of the criteria used to establish that the unit qualifies as a cogeneration facility under section 3(18)(B) of the Federal Power Act (16 U.S.C. 796(18)(B)) and that the waste material the unit is proposed to burn is homogeneous.

§ 60.2745 Where and in what format must I keep my records?

All records must be available onsite in either paper copy or computer-readable format that can be printed upon request, unless an alternative format is approved by the Administrator.

§ 60.2750 What reports must I submit?

See table 5 of this subpart for a summary of the reporting requirements.

§ 60.2755 When must I submit my waste management plan?

You must submit the waste management plan no later than the date specified in table 1 of this subpart for submittal of the final control plan.

§ 60.2760 What information must I submit following my initial performance test?

You must submit the information specified in paragraphs (a) through (c) of this section no later than 60 days following the initial performance test. All reports must be signed by the facilities manager:

(a) The complete test report for the initial performance test results obtained under § 60.2700, as applicable;

(b) The values for the site-specific operating limits established in § 60.2675 or § 60.2680; and

(c) If you are using a fabric filter to comply with the emission limitations, documentation that a bag leak detection system has been installed and is being operated, calibrated, and maintained as required by § 60.2730(b).

§ 60.2765 When must I submit my annual report?

You must submit an annual report no later than 12 months following the submission of the information in § 60.2760. You must submit subsequent reports no more than 12 months following the previous report. (If the unit is subject to permitting requirements under title V of the Clean Air Act, you may be required by the permit to submit these reports more frequently.)

§ 60.2770 What information must I include in my annual report?

The annual report required under § 60.2765 must include the ten items listed in paragraphs (a) through (j) of this section. If you have a deviation from the operating limits or the emission limitations, you must also submit deviation reports as specified in §§ 60.2775, 60.2780, and 60.2785:

(a) Company name and address;

(b) Statement by a responsible official, with that official's name, title, and signature, certifying the accuracy of the content of the report;

(c) Date of report and beginning and ending dates of the reporting period;

(d) The values for the operating limits established pursuant to § 60.2675 or § 60.2680;

(e) If no deviation from any emission limitation or operating limit that applies to you has been reported, a statement that there was no deviation from the emission limitations or operating limits during the reporting period;

(f) The highest recorded 3-hour average and the lowest recorded 3-hour average, as applicable, for each operating parameter recorded for the calendar year being reported;

(g) Information recorded under § 60.2740(b)(6) and (c) through (e) for the calendar year being reported;

(h) For each performance test conducted during the reporting period, if any performance test is conducted, the process unit(s) tested, the pollutant(s) tested and the date that such performance test was conducted. Submit, following the procedure specified in § 60.2795(b)(1), the performance test report no later than the date that you submit the annual report;

(i) If you met the requirements of § 60.2720(a) or (b), and did not conduct a performance test during the reporting period, you must state that you met the requirements of § 60.2720(a) or (b), and, therefore, you were not required to conduct a performance test during the reporting period;

(j) Documentation of periods when all qualified CISWI unit operators were unavailable for more than 8 hours, but less than 2 weeks;

(k) If you had a malfunction during the reporting period, the compliance report must include the number, duration, and a brief description for each type of malfunction that occurred during the reporting period and that caused or may have caused any applicable emission limitation to be exceeded. The report must also include a description of actions taken by an owner or operator during a malfunction of an affected source to minimize emissions in accordance with § 60.11(d), including actions taken to correct a malfunction;

(l) For each deviation from an emission or operating limitation that occurs for a CISWI unit for which you are not using a CMS to comply with the emission or operating limitations in this subpart, the annual report must contain the following information:

(1) The total operating time of the CISWI unit at which the deviation occurred during the reporting period; and

(2) Information on the number, duration, and cause of deviations (including unknown cause, if applicable), as applicable, and the corrective action taken.

(m) If there were periods during which the continuous monitoring system, including the CEMS, was out of control as specified in paragraph (o) of this section, the annual report must contain the following information for each deviation from an emission or operating limitation occurring for a CISWI unit for which you are using a continuous monitoring system to comply with the emission and operating limitations in this subpart:

(1) The date and time that each malfunction started and stopped;

(2) The date, time, and duration that each CMS was inoperative, except for zero (low-level) and high-level checks;

(3) The date, time, and duration that each continuous monitoring system was out-of-control, including start and end dates and hours and descriptions of corrective actions taken;

(4) The date and time that each deviation started and stopped, and whether each deviation occurred during a period of malfunction or during another period;

(5) A summary of the total duration of the deviation during the reporting period, and the total duration as a percent of the total source operating time during that reporting period;

(6) A breakdown of the total duration of the deviations during the reporting period into those that are due to control equipment problems, process problems, other known causes, and other unknown causes;

(7) A summary of the total duration of continuous monitoring system downtime during the reporting period, and the total duration of continuous monitoring system downtime as a percent of the total operating time of the CISWI unit at which the continuous monitoring system downtime occurred during that reporting period;

(8) An identification of each parameter and pollutant that was monitored at the CISWI unit;

(9) A brief description of the CISWI unit;

(10) A brief description of the continuous monitoring system;

(11) The date of the latest continuous monitoring system certification or audit; and

(12) A description of any changes in continuous monitoring system, processes, or controls since the last reporting period.

(n) If there were periods during which the continuous monitoring system, including the CEMS, was not out of control as specified in paragraph (o) of this section, a statement that there were not periods during which the continuous monitoring system was out of control during the reporting period.

(o) A continuous monitoring system is out of control if any of the following occur:

(1) The zero (low-level), mid-level (if applicable), or high-level calibration drift exceeds two times the applicable calibration drift specification in the applicable performance specification or in the relevant standard;

(2) The continuous monitoring system fails a performance test audit (*e.g.,* cylinder gas audit), relative accuracy audit, relative accuracy test audit, or linearity test audit; and

(3) The continuous opacity monitoring system calibration drift exceeds two times the limit in the applicable performance specification in the relevant standard.

(p) For energy recovery units, include the annual heat input and average annual heat input rate of all fuels being burned in the unit to verify which subcategory of energy recovery unit applies.

§ 60.2775 What else must I report if I have a deviation from the operating limits or the emission limitations?

(a) You must submit a deviation report if any recorded 3-hour average parameter level is above the maximum operating limit or below the minimum operating limit established under this subpart, if the bag leak detection system alarm sounds for more than 5 percent of the operating time for the 6-month reporting period, or if a performance test was conducted that deviated from any emission limitation.

(b) The deviation report must be submitted by August 1 of that year for data collected during the first half of the calendar year (January 1 to June 30), and by February 1 of the following year for data you collected during the second half of the calendar year (July 1 to December 31).

§ 60.2780 What must I include in the deviation report?

In each report required under § 60.2775, for any pollutant or parameter that deviated from the emission limitations or operating limits specified in this subpart, include the four items described in paragraphs (a) through (d) of this section:

(a) The calendar dates and times your unit deviated from the emission limitations or operating limit requirements;

(b) The averaged and recorded data for those dates;

(c) Durations and causes of the following:

(1) Each deviation from emission limitations or operating limits and your corrective actions; and

(2) Bypass events and your corrective actions.

(d) A copy of the operating limit monitoring data during each deviation and for any test report that documents the emission levels the process unit(s) tested, the pollutant(s) tested and the date that the performance test was conducted. Submit, following the procedure specified in § 60.2795(b)(1), the performance test report no later than the date that you submit the deviation report.

§ 60.2785 What else must I report if I have a deviation from the requirement to have a qualified operator accessible?

(a) If all qualified operators are not accessible for 2 weeks or more, you must take the two actions in paragraphs (a)(1) and (2) of this section:

(1) Submit a notification of the deviation within 10 days that includes the three items in paragraphs (a)(1)(i) through (iii) of this section:

(i) A statement of what caused the deviation;

(ii) A description of what you are doing to ensure that a qualified operator is accessible; and

(iii) The date when you anticipate that a qualified operator will be available.

(2) Submit a status report to the Administrator every 4 weeks that includes the three items in paragraphs (a)(2)(i) through (iii) of this section:

(i) A description of what you are doing to ensure that a qualified operator is accessible;

(ii) The date when you anticipate that a qualified operator will be accessible; and

(iii) Request approval from the Administrator to continue operation of the CISWI unit.

(b) If your unit was shut down by the Administrator, under the provisions of § 60.2665(b)(2), due to a failure to provide an accessible qualified operator, you must notify the Administrator that you are resuming operation once a qualified operator is accessible.

§ 60.2790 Are there any other notifications or reports that I must submit?

(a) Yes. You must submit notifications as provided by § 60.7.

(b) If you cease combusting solid waste but continue to operate, you must provide 30 days prior notice of the effective date of the waste-to-fuel switch, consistent with § 60.2710(a). The notification must identify:

(1) The name of the owner or operator of the CISWI unit, the location of the source, the emissions unit(s) that will cease burning solid waste, and the date of the notice;

(2) The currently applicable subcategory under this subpart, and any 40 CFR part 63 subpart and subcategory that will be applicable after you cease combusting solid waste;

(3) The fuel(s), non-waste material(s) and solid waste(s) the CISWI unit is currently combusting and has combusted over the past 6 months, and the fuel(s) or non-waste materials the unit will commence combusting;

(4) The date on which you became subject to the currently applicable emission limits; and

(5) The date upon which you will cease combusting solid waste, and the date (if different) that you intend for any new requirements to become applicable (*i.e.*, the effective date of the waste-to-fuel switch), consistent with paragraphs (b)(2) and (3) of this section.

§ 60.2795 In what form can I submit my reports?

(a) Submit initial, annual and deviation reports electronically on or before the submittal due dates. Submit the reports to the EPA via the Compliance and Emissions Data Reporting Interface (CEDRI). (CEDRI can be accessed through the EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov/*).) Use the appropriate electronic report in CEDRI for this subpart or an alternate electronic file format consistent with the extensible markup language (XML) schema listed on the CEDRI Web site (*https://www3.epa.gov/ttn/chief/cedri/index.html*), once the XML schema is available. If the reporting form specific to this subpart is not available in CEDRI at the time that the report is due, submit the report to the Administrator at the appropriate address listed in § 60.4. Once the form has been available in CEDRI for 90 calendar days, you must begin submitting all subsequent reports via CEDRI. The reports must be submitted by the deadlines specified in this subpart, regardless of the method in which the report is submitted.

(b) Submit results of each performance test and CEMS performance evaluation required by this subpart as follows:

(1) Within 60 days after the date of completing each performance test (*see* § 60.8) required by this subpart, you must submit the results of the performance test following the procedure specified in either paragraph (b)(1)(i) or (b)(1)(ii) of this section:

(i) For data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT Web site (*https://www3.epa.gov/ttn/chief/ert/ert_info.html*) at the time of the test, you must submit the results of the performance test to the EPA via the CEDRI. (CEDRI can be accessed through the EPA's CDX (*https://cdx.epa.gov/*).) Performance test data must be submitted in a file format generated through the use of the EPA's ERT or an alternate electronic file format consistent with the XML schema listed on the EPA's ERT Web site. If you claim that some of the performance test information being submitted is confidential business information (CBI), you must submit a complete file generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT Web site, including information claimed to be CBI, on a compact disc, flash drive, or other commonly used electronic storage media to the EPA. The electronic media must be clearly marked as CBI and mailed to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same ERT or alternate file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph; and

(ii) For data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT Web site at the time of the test, you must submit the results of the performance test to the Administrator at the appropriate address listed in § 60.4.

(2) Within 60 days after the date of completing each continuous emissions monitoring system performance evaluation you must submit the results of the performance evaluation following the procedure specified in either paragraph (b)(1) or (b)(2) of this section:

(i) For performance evaluations of continuous monitoring systems measuring relative accuracy test audit (RATA) pollutants that are supported by the EPA's ERT as listed on the EPA's ERT Web site at the time of the evaluation, you must submit the results of the performance evaluation to the EPA via the CEDRI. (CEDRI can be accessed through the EPA's CDX.) Performance evaluation data must be submitted in a file format generated through the use of the EPA's ERT or an alternate file format consistent with the XML schema listed on the EPA's ERT Web site. If you claim that some of the performance evaluation information being submitted is CBI, you must submit a complete file generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT Web site, including information claimed to be CBI, on a compact disc, flash drive, or other commonly used electronic storage media to the EPA. The electronic storage media must be clearly marked as CBI and mailed to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same ERT or alternate file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph; and

(ii) For any performance evaluations of continuous monitoring systems measuring RATA pollutants that are not supported by the EPA's ERT as listed on the EPA's ERT Web site at the time of the evaluation, you must submit the results of the performance evaluation to the Administrator at the appropriate address listed in § 60.4.

§ 60.2800 Can reporting dates be changed?

If the Administrator agrees, you may change the semiannual or annual reporting dates. See § 60.19(c) for procedures to seek approval to change your reporting date.

Model Rule—Title V Operating Permits

§ 60.2805 Am I required to apply for and obtain a Title V operating permit for my unit?

Yes. Each CISWI unit and air curtain incinerator subject to standards under this subpart must operate pursuant to a permit issued under Clean Air Act sections 129(e) and Title V.

Model Rule—Air Curtain Incinerators

§ 60.2810 What is an air curtain incinerator?

(a) An air curtain incinerator operates by forcefully projecting a curtain of air across an open chamber or open pit in which combustion occurs. Incinerators of this type can be constructed above or below ground and with or without refractory walls and floor. (Air curtain incinerators are not to be confused with conventional combustion devices with enclosed fireboxes and controlled air technology such as mass burn, modular, and fluidized bed combustors.)

(b) Air curtain incinerators that burn only the materials listed in paragraphs (b)(1) through (3) of this section are only required to meet the requirements under § 60.2805 and under "Air Curtain Incinerators" (§§ 60.2810 through 60.2870):

(1) 100 percent wood waste;

(2) 100 percent clean lumber; and

(3) 100 percent mixture of only wood waste, clean lumber, and/or yard waste.

§ 60.2815 What are my requirements for meeting increments of progress and achieving final compliance?

If you plan to achieve compliance more than 1 year following the effective date of state plan approval, you must meet the two increments of progress specified in paragraphs (a) and (b) of this section:

(a) Submit a final control plan; and

(b) Achieve final compliance.

§ 60.2820 When must I complete each increment of progress?

Table 1 of this subpart specifies compliance dates for each of the increments of progress.

§ 60.2825 What must I include in the notifications of achievement of increments of progress?

Your notification of achievement of increments of progress must include the three items described in paragraphs (a) through (c) of this section:

(a) Notification that the increment of progress has been achieved;

(b) Any items required to be submitted with each increment of progress (see § 60.2840); and

(c) Signature of the owner or operator of the incinerator.

§ 60.2830 When must I submit the notifications of achievement of increments of progress?

Notifications for achieving increments of progress must be postmarked no later than 10 business days after the compliance date for the increment.

§ 60.2835 What if I do not meet an increment of progress?

If you fail to meet an increment of progress, you must submit a notification to the Administrator postmarked within 10 business days after the date for that increment of progress in table 1 of this subpart. You must inform the Administrator that you did not meet the increment, and you must continue to submit reports each subsequent calendar month until the increment of progress is met.

§ 60.2840 How do I comply with the increment of progress for submittal of a control plan?

For your control plan increment of progress, you must satisfy the two requirements specified in paragraphs (a) and (b) of this section:

(a) Submit the final control plan, including a description of any devices for air pollution control and any process changes that you will use to comply with the emission limitations and other requirements of this subpart; and

(b) Maintain an onsite copy of the final control plan.

§ 60.2845 How do I comply with the increment of progress for achieving final compliance?

For the final compliance increment of progress, you must complete all process changes and retrofit construction of control devices, as specified in the final control plan, so that, if the affected incinerator is brought online, all necessary process changes and air pollution control devices would operate as designed.

§ 60.2850 What must I do if I close my air curtain incinerator and then restart it?

(a) If you close your incinerator but will reopen it prior to the final compliance date in your state plan, you must meet the increments of progress specified in § 60.2815.

(b) If you close your incinerator but will restart it after your final compliance date, you must complete emission control retrofits and meet the emission limitations on the date your incinerator restarts operation.

§ 60.2855 What must I do if I plan to permanently close my air curtain incinerator and not restart it?

If you plan to close your incinerator rather than comply with the state plan, submit a closure notification, including the date of closure, to the Administrator by the date your final control plan is due.

§ 60.2860 What are the emission limitations for air curtain incinerators?

After the date the initial stack test is required or completed (whichever is earlier), you must meet the limitations in paragraphs (a) and (b) of this section:

(a) Maintain opacity to less than or equal to 10 percent opacity (as determined by the average of three 1-hour blocks consisting of ten 6-minute average opacity values), except as described in paragraph (b) of this section; and

(b) Maintain opacity to less than or equal to 35 percent opacity (as determined by the average of three 1-hour blocks consisting of ten 6-minute average opacity values) during the startup period that is within the first 30 minutes of operation.

§ 60.2865 How must I monitor opacity for air curtain incinerators?

(a) Use Method 9 of appendix A of this part to determine compliance with the opacity limitation.

(b) Conduct an initial test for opacity as specified in § 60.8 no later than 180 days after your final compliance date.

(c) After the initial test for opacity, conduct annual tests no more than 12 calendar months following the date of your previous test.

§ 60.2870 What are the recordkeeping and reporting requirements for air curtain incinerators?

(a) Keep records of results of all initial and annual opacity tests onsite in either paper copy or electronic format, unless the Administrator approves another format, for at least 5 years.

(b) Make all records available for submittal to the Administrator or for an inspector's onsite review.

(c) Submit an initial report no later than 60 days following the initial opacity test that includes the information specified in paragraphs (c)(1) and (2) of this section:

(1) The types of materials you plan to combust in your air curtain incinerator; and

(2) The results (as determined by the average of three 1-hour blocks consisting of ten 6-minute average opacity values) of the initial opacity tests.

(d) Submit annual opacity test results within 12 months following the previous report.

(e) Submit initial and annual opacity test reports as electronic or paper copy on or before the applicable submittal date and keep a copy onsite for a period of 5 years.

Model Rule—Definitions

§ 60.2875 What definitions must I know?

Terms used but not defined in this subpart are defined in the Clean Air Act and subparts A and B of this part.

30-day rolling average means the arithmetic mean of the previous 720 hours of valid operating data. Valid data excludes periods when this unit is not operating. The 720 hours should be consecutive, but not necessarily continuous if operations are intermittent.

Administrator means the Administrator of the U.S. Environmental Protection Agency or his/her authorized representative or Administrator of a State Air Pollution Control Agency.

Agricultural waste means vegetative agricultural materials such as nut and grain hulls and chaff (*e.g.*, almond, walnut, peanut, rice, and wheat), bagasse, orchard prunings, corn stalks, coffee bean hulls and grounds, and other vegetative waste materials generated as a result of agricultural operations.

Air curtain incinerator means an incinerator that operates by forcefully projecting a curtain of air across an open chamber or pit in which combustion occurs. Incinerators of this type can be constructed above or below ground and with or without refractory walls and floor. (Air curtain incinerators are not to be confused with conventional combustion devices with enclosed fireboxes and controlled air technology such as mass burn, modular, and fluidized bed combustors.)

Annual heat input means the heat input for the 12 months preceding the compliance demonstration.

Auxiliary fuel means natural gas, liquified petroleum gas, fuel oil, or diesel fuel.

Average annual heat input rate means annual heat input divided by the hours of operation for the 12 months preceding the compliance demonstration.

Bag leak detection system means an instrument that is capable of monitoring particulate matter loadings in the exhaust of a fabric filter (*i.e.*, baghouse) in order to detect bag failures. A bag leak detection system includes, but is not limited to, an instrument that operates on triboelectric, light scattering, light transmittance, or other principle to monitor relative particulate matter loadings.

Burn-off oven means any rack reclamation unit, part reclamation unit, or drum reclamation unit. A burn-off oven is not an incinerator, waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Bypass stack means a device used for discharging combustion gases to avoid severe damage to the air pollution control device or other equipment.

Calendar quarter means three consecutive months (nonoverlapping) beginning on: January 1, April 1, July 1, or October 1.

Calendar year means 365 consecutive days starting on January 1 and ending on December 31.

CEMS data during startup and shutdown means the following:

(1) For incinerators and small remote incinerators: CEMS data collected during the first hours of operation of a CISWI unit startup from a cold start until waste is fed into the unit and the hours of operation following the cessation of waste material being fed to the CISWI unit during a unit shutdown. For each startup event, the length of time that CEMS data may be claimed as being CEMS data during startup must be 48 operating hours or less. For each shutdown event, the length of time that CEMS data may be claimed as being CEMS data during shutdown must be 24 operating hours or less;

(2) For energy recovery units: CEMS data collected during the startup or shutdown periods of operation. Startup begins with either the first-ever firing of fuel in a boiler or process heater for the purpose of supplying useful thermal energy (such as steam or heat) for heating, cooling or process purposes, or producing electricity, or the firing of fuel in a boiler or process heater for any purpose after a shutdown event. Startup ends four hours after when the boiler or process heater makes useful thermal energy (such as heat or steam) for heating, cooling, or process purposes, or generates electricity, whichever is earlier. Shutdown begins when the boiler or process heater no longer makes useful thermal energy (such as heat or steam) for heating, cooling, or process purposes and/or generates electricity or when no fuel is being fed to the boiler or process heater, whichever is earlier. Shutdown ends when the boiler or process heater no longer makes useful thermal energy (such as steam or heat) for heating, cooling, or process purposes and/or generates electricity, and no fuel is being combusted in the boiler or process heater; and

(3) For waste-burning kilns: CEMS data collected during the periods of kiln operation that do not include normal operations. Startup means the time from when a shutdown kiln first begins firing fuel until it begins producing clinker. Startup begins when a shutdown kiln turns on the induced draft fan and begins firing fuel in the main burner. Startup ends when feed is being continuously introduced into the kiln for at least 120 minutes or when the feed rate exceeds 60 percent of the kiln design limitation rate, whichever occurs first. Shutdown means the cessation of kiln operation. Shutdown begins when feed to the kiln is halted and ends when continuous kiln rotation ceases.

Chemical recovery unit means combustion units burning materials to recover chemical constituents or to produce chemical compounds where there is an existing commercial market for such recovered chemical constituents or compounds. A chemical recovery unit is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart. The following seven types of units are considered chemical recovery units:

(1) Units burning only pulping liquors (*i.e.*, black liquor) that are reclaimed in a pulping liquor recovery process and reused in the pulping process;

(2) Units burning only spent sulfuric acid used to produce virgin sulfuric acid;

(3) Units burning only wood or coal feedstock for the production of charcoal;

(4) Units burning only manufacturing byproduct streams/residue containing catalyst metals that are reclaimed and reused as catalysts or used to produce commercial grade catalysts;

(5) Units burning only coke to produce purified carbon monoxide that is used as an intermediate in the production of other chemical compounds;

(6) Units burning only hydrocarbon liquids or solids to produce hydrogen, carbon monoxide, synthesis gas, or other gases for use in other manufacturing processes; and

(7) Units burning only photographic film to recover silver.

Chemotherapeutic waste means waste material resulting from the production or use of antineoplastic agents used for the purpose of stopping or reversing the growth of malignant cells.

Clean lumber means wood or wood products that have been cut or shaped and include wet, air-dried, and kiln-dried wood products. Clean lumber does not include wood products that have been painted, pigment-stained, or pressure-treated by compounds such as chromate copper arsenate, pentachlorophenol, and creosote.

Commercial and industrial solid waste incineration (CISWI) unit means any distinct operating unit of any commercial or industrial facility that combusts, or has combusted in the preceding 6 months, any solid waste as that term is defined in 40 CFR part 241. If the operating unit burns materials other than traditional fuels as defined in § 241.2 that have been discarded, and you do not keep and produce records as required by § 60.2740(u), the operating unit is a CISWI unit. While not all CISWI units will include all of the following components, a CISWI unit includes, but is not limited to, the solid waste feed system, grate system, flue gas system, waste heat recovery equipment, if any, and bottom ash system. The CISWI unit does not include air pollution control equipment or the stack. The CISWI unit boundary starts at the solid waste hopper (if applicable) and extends through two areas: The combustion unit flue gas system, which ends immediately after the last combustion chamber or after the waste heat recovery equipment, if any; and the combustion unit bottom ash system, which ends at the truck loading station or similar equipment that transfers the ash to final disposal. The CISWI unit includes all ash handling systems connected to the bottom ash handling system.

Contained gaseous material means gases that are in a container when that container is combusted.

Continuous emission monitoring system (CEMS) means the total equipment that may be required to meet the data acquisition and availability requirements of this subpart, used to sample, condition (if applicable), analyze, and provide a record of emissions.

Continuous monitoring system (CMS) means the total equipment, required under the emission monitoring sections in applicable subparts, used to sample and condition (if applicable), to analyze, and to provide a permanent record of emissions or process parameters. A particulate matter continuous parameter monitoring system (PM CPMS) is a type of CMS.

Cyclonic burn barrel means a combustion device for waste materials that is attached to a 55 gallon, open-head drum. The device consists of a lid, which fits onto and encloses the drum, and a blower that forces combustion air into the drum in a cyclonic manner to enhance the mixing of waste material and air. A cyclonic burn barrel is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Deviation means any instance in which an affected source subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart, including but not limited to any emission limitation, operating limit, or operator qualification and accessibility requirements; and

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any affected source required to obtain such a permit.

Dioxins/furans means tetra-through octachlorinated dibenzo-p-dioxins and dibenzofurans.

Discard means, for purposes of this subpart and 40 CFR part 60, subpart DDDD, only, burned in an incineration unit without energy recovery.

Drum reclamation unit means a unit that burns residues out of drums (*e.g.,* 55 gallon drums) so that the drums can be reused.

Dry scrubber means an add-on air pollution control system that injects dry alkaline sorbent (dry injection) or sprays an alkaline sorbent (spray dryer) to react with and neutralize acid gas in the exhaust stream forming a dry powder material. Sorbent injection systems in fluidized bed boilers and process heaters are included in this definition. A dry scrubber is a dry control system.

Energy recovery means the process of recovering thermal energy from combustion for useful purposes such as steam generation or process heating.

Energy recovery unit means a combustion unit combusting solid waste (as that term is defined by the Administrator in 40 CFR part 241) for energy recovery. Energy recovery units include units that would be considered boilers and process heaters if they did not combust solid waste.

Energy recovery unit designed to burn biomass (Biomass) means an energy recovery unit that burns solid waste, biomass, and non-coal solid materials but less than 10 percent coal, on a heat input basis on an annual average, either alone or in combination with liquid waste, liquid fuel or gaseous fuels.

Energy recovery unit designed to burn coal (Coal) means an energy recovery unit that burns solid waste and at least 10 percent coal on a heat input basis on an annual average, either alone or in combination with liquid waste, liquid fuel or gaseous fuels.

Energy recovery unit designed to burn liquid waste materials and gas (Liquid/gas) means an energy recovery unit that burns a liquid waste with liquid or gaseous fuels not combined with any solid fuel or waste materials.

Energy recovery unit designed to burn solid materials (Solids) includes energy recovery units designed to burn coal and energy recovery units designed to burn biomass

Fabric filter means an add-on air pollution control device used to capture particulate matter by filtering gas streams through filter media, also known as a baghouse.

Foundry sand thermal reclamation unit means a type of part reclamation unit that removes coatings that are on foundry sand. A foundry sand thermal reclamation unit is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Incinerator means any furnace used in the process of combusting solid waste (as that term is defined by the Administrator in 40 CFR part 241) for the purpose of reducing the volume of the waste by removing combustible matter. Incinerator designs include single chamber and two-chamber.

In-line coal mill means those coal mills using kiln exhaust gases in their process. Coal mills with a heat source other than the kiln or coal mills using exhaust gases from the clinker cooler alone are not an in-line coal mill.

In-line kiln/raw mill means a system in a Portland Cement production process where a dry kiln system is integrated with the raw mill so that all or a portion of the kiln exhaust gases are used to perform the drying operation of the raw mill, with no auxiliary heat source used. In this system the kiln is capable of operating without the raw mill operating, but the raw mill cannot operate without the kiln gases, and consequently, the raw mill does not generate a separate exhaust gas stream.

Kiln means an oven or furnace, including any associated preheater or precalciner devices, in-line raw mills, in-line coal mills or alkali bypasses used for processing a substance by burning, firing or drying. Kilns include cement kilns that produce clinker by heating limestone and other materials for subsequent production of Portland Cement. Because the alkali bypass, in-line raw mill and in-line coal mill are considered an integral part of the kiln, the kiln emissions limits also apply to the exhaust of the alkali bypass, in-line raw mill and in-line coal mill.

Laboratory analysis unit means units that burn samples of materials for the purpose of chemical or physical analysis. A laboratory analysis unit is not an incinerator, waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Load fraction means the actual heat input of an energy recovery unit divided by heat input during the performance test that established the minimum sorbent injection rate or minimum activated carbon injection rate, expressed as a fraction (*e.g.*, for 50 percent load the load fraction is 0.5).

Low-level radioactive waste means waste material which contains radioactive nuclides emitting primarily beta or gamma radiation, or both, in concentrations or quantities that exceed applicable federal or state standards for unrestricted release. Low-level radioactive waste is not high-level radioactive waste, spent nuclear fuel, or by-product material as defined by the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)(2)).

Malfunction means any sudden, infrequent, and not reasonably preventable failure of air pollution control equipment, process equipment, or a process to operate in a normal or usual manner. Failures that are caused, in part, by poor maintenance or careless operation are not malfunctions.

Minimum voltage or amperage means 90 percent of the lowest test-run average voltage or amperage to the electrostatic precipitator measured during the most recent particulate matter or mercury performance test demonstrating compliance with the applicable emission limits.

Modification or *modified CISWI unit* means a CISWI unit that has been changed later than August 7, 2013, and that meets one of two criteria:

(1) The cumulative cost of the changes over the life of the unit exceeds 50 percent of the original cost of building and installing the CISWI unit (not including the cost of land) updated to current costs (current dollars). To determine what systems are within the boundary of the CISWI unit used to calculate these costs, see the definition of CISWI unit; and

(2) Any physical change in the CISWI unit or change in the method of operating it that increases the amount of any air pollutant emitted for which section 129 or section 111 of the Clean Air Act has established standards.

Municipal solid waste or municipal-type solid waste means household, commercial/retail, or institutional waste. Household waste includes material discarded by residential dwellings, hotels, motels, and other similar permanent or temporary housing. Commercial/retail waste includes material discarded by stores, offices, restaurants, warehouses, nonmanufacturing activities at industrial facilities, and other similar establishments or facilities. Institutional waste includes materials discarded by schools, by hospitals (nonmedical), by nonmanufacturing activities at prisons and government facilities, and other similar establishments or facilities. Household, commercial/retail, and institutional waste does include yard waste and refuse-derived fuel. Household, commercial/retail, and institutional waste does not include used oil; sewage sludge; wood pallets; construction, renovation, and demolition wastes (which include railroad ties and telephone poles); clean wood; industrial process or manufacturing wastes; medical waste; or motor vehicles (including motor vehicle parts or vehicle fluff).

Opacity means the degree to which emissions reduce the transmission of light and obscure the view of an object in the background.

Operating day means a 24-hour period between 12:00 midnight and the following midnight during which any amount of solid waste is combusted at any time in the CISWI unit.

Oxygen analyzer system means all equipment required to determine the oxygen content of a gas stream and used to monitor oxygen in the boiler or process heater flue gas, boiler/process heater, firebox, or other appropriate location. This definition includes oxygen trim systems and certified oxygen CEMS. The source owner or operator is responsible to install, calibrate, maintain, and operate the oxygen analyzer system in accordance with the manufacturer's recommendations.

Oxygen trim system means a system of monitors that is used to maintain excess air at the desired level in a combustion device over its operating range. A typical system consists of a flue gas oxygen and/or carbon monoxide monitor that automatically provides a feedback signal to the combustion air controller or draft controller.

Part reclamation unit means a unit that burns coatings off parts (*e.g.*, tools, equipment) so that the parts can be reconditioned and reused.

Particulate matter means total particulate matter emitted from CISWI units as measured by Method 5 or Method 29 of appendix A of this part.

Pathological waste means waste material consisting of only human or animal remains, anatomical parts, and/or tissue, the bags/containers used to collect and transport the waste material, and animal bedding (if applicable).

Performance evaluation means the conduct of relative accuracy testing, calibration error testing, and other measurements used in validating the continuous monitoring system data.

Performance test means the collection of data resulting from the execution of a test method (usually three emission test runs) used to demonstrate compliance with a relevant emission standard as specified in the performance test section of the relevant standard.

Process change means any of the following physical or operational changes:

(1) A physical change (maintenance activities excluded) to the CISWI unit which may increase the emission rate of any air pollutant to which a standard applies;

(2) An operational change to the CISWI unit where a new type of non-hazardous secondary material is being combusted;

(3) A physical change (maintenance activities excluded) to the air pollution control devices used to comply with the emission limits for the CISWI unit (*e.g.*, replacing an electrostatic precipitator with a fabric filter); and

(4) An operational change to the air pollution control devices used to comply with the emission limits for the affected CISWI unit (*e.g.*, change in the sorbent injection rate used for activated carbon injection).

Rack reclamation unit means a unit that burns the coatings off racks used to hold small items for application of a coating. The unit burns the coating overspray off the rack so the rack can be reused.

Raw mill means a ball or tube mill, vertical roller mill or other size reduction equipment, that is not part of an in-line kiln/raw mill, used to grind feed to the appropriate size. Moisture may be added or removed from the feed during the grinding operation. If the raw mill is used to remove moisture from feed materials, it is also, by definition, a raw material dryer. The raw mill also includes the air separator associated with the raw mill.

Reconstruction means rebuilding a CISWI unit and meeting two criteria:

(1) The reconstruction begins on or after August 7, 2013; and

(2) The cumulative cost of the construction over the life of the incineration unit exceeds 50 percent of the original cost of building and installing the CISWI unit (not including land) updated to current costs (current

dollars). To determine what systems are within the boundary of the CISWI unit used to calculate these costs, see the definition of CISWI unit.

Refuse-derived fuel means a type of municipal solid waste produced by processing municipal solid waste through shredding and size classification. This includes all classes of refuse-derived fuel including two fuels:

(1) Low-density fluff refuse-derived fuel through densified refuse-derived fuel; and

(2) Pelletized refuse-derived fuel.

Responsible official means one of the following:

(1) For a corporation: A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation, or a duly authorized representative of such person if the representative is responsible for the overall operation of one or more manufacturing, production, or operating facilities applying for or subject to a permit and either:

(i) The facilities employ more than 250 persons or have gross annual sales or expenditures exceeding $25 million (in second quarter 1980 dollars); or

(ii) The delegation of authority to such representatives is approved in advance by the permitting authority;

(2) For a partnership or sole proprietorship: a general partner or the proprietor, respectively;

(3) For a municipality, state, federal, or other public agency: Either a principal executive officer or ranking elected official. For the purposes of this part, a principal executive officer of a Federal agency includes the chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency (*e.g.*, a Regional Administrator of EPA); or

(4) For affected facilities:

(i) The designated representative in so far as actions, standards, requirements, or prohibitions under Title IV of the Clean Air Act or the regulations promulgated thereunder are concerned; or

(ii) The designated representative for any other purposes under part 60.

Shutdown means, for incinerators and small, remote incinerators, the period of time after all waste has been combusted in the primary chamber.

Small, remote incinerator means an incinerator that combusts solid waste (as that term is defined by the Administrator in 40 CFR part 241) and combusts 3 tons per day or less solid waste and is more than 25 miles driving distance to the nearest municipal solid waste landfill.

Soil treatment unit means a unit that thermally treats petroleum-contaminated soils for the sole purpose of site remediation. A soil treatment unit may be direct-fired or indirect fired. A soil treatment unit is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Solid waste means the term solid waste as defined in 40 CFR 241.2.

Solid waste incineration unit means a distinct operating unit of any facility which combusts any solid waste (as that term is defined by the Administrator in 40 CFR part 241) material from commercial or industrial establishments or the general public (including single and multiple residences, hotels and motels). Such term does not include incinerators or other units required to have a permit under section 3005 of the Solid Waste Disposal Act. The term "solid waste incineration unit" does not include:

(1) Materials recovery facilities (including primary or secondary smelters) which combust waste for the primary purpose of recovering metals;

(2) Qualifying small power production facilities, as defined in section 3(17)(C) of the Federal Power Act (16 U.S.C. 769(17)(C)), or qualifying cogeneration facilities, as defined in section 3(18)(B) of the Federal Power Act (16 U.S.C. 796(18)(B)), which burn homogeneous waste (such as units which burn tires or used oil, but not including refuse-derived fuel) for the production of electric energy or in the case of qualifying cogeneration facilities which burn homogeneous waste for the production of electric energy and steam or forms of useful energy (such as heat) which are used for industrial, commercial, heating or cooling purposes; or

(3) Air curtain incinerators provided that such incinerators only burn wood wastes, yard wastes and clean lumber and that such air curtain incinerators comply with opacity limitations to be established by the Administrator by rule.

Space heater means a unit that meets the requirements of 40 CFR 279.23. A space heater is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Standard conditions, when referring to units of measure, means a temperature of 68 °F (20 °C) and a pressure of 1 atmosphere (101.3 kilopascals).

Startup period means, for incinerators and small, remote incinerators, the period of time between the activation of the system and the first charge to the unit.

Useful thermal energy means energy (*i.e.*, steam, hot water, or process heat) that meets the minimum operating temperature and/or pressure required by any energy use system that uses energy provided by the affected energy recovery unit.

Waste-burning kiln means a kiln that is heated, in whole or in part, by combusting solid waste (as the term is defined by the Administrator in 40 CFR part 241). Secondary materials used in Portland cement kilns shall not be deemed to be combusted unless they are introduced into the flame zone in the hot end of the kiln or mixed with the precalciner fuel.

Wet scrubber means an add-on air pollution control device that uses an aqueous or alkaline scrubbing liquor to collect particulate matter (including nonvaporous metals and condensed organics) and/or to absorb and neutralize acid gases.

Wood waste means untreated wood and untreated wood products, including tree stumps (whole or chipped), trees, tree limbs (whole or chipped), bark, sawdust, chips, scraps, slabs, millings, and shavings. Wood waste does not include:

(1) Grass, grass clippings, bushes, shrubs, and clippings from bushes and shrubs from residential, commercial/retail, institutional, or industrial sources as part of maintaining yards or other private or public lands;

(2) Construction, renovation, or demolition wastes; or

(3) Clean lumber.

Table 1 to Subpart DDDD of Part 60—Model Rule—Increments of Progress and Compliance Schedules

Comply with these increments of progress	By these dates[1]
Increment 1—Submit final control plan.	(Dates to be specified in state plan).
Increment 2—Final compliance.	(Dates to be specified in state plan).[2]

[1] Site-specific schedules can be used at the discretion of the state.

[2] The date can be no later than 3 years after the effective date of state plan approval or December 1, 2005 for CISWI units that commenced construction on or before November 30, 1999. The date can be no later than 3 years after the effective date of approval of a revised state plan or February 7, 2018, for CISWI units that commenced construction on or before June 4, 2010.

Table 2 to Subpart DDDD of Part 60—Model Rule—Emission Limitations That Apply to Incinerators Before

[Date to be specified in state plan][2]

For the air pollutant	You must meet this emission limitation[1]	Using this averaging time	And determining compliance using this method
Cadmium	0.004 milligrams per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Performance test (Method 29 of appendix A of this part).
Carbon monoxide	157 parts per million by dry volume	3-run average (1 hour minimum sample time per run).	Performance test (Method 10, 10A, or 10B, of appendix A of this part).
Dioxins/furans (toxic equivalency basis).	0.41 nanograms per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Performance test (Method 23 of appendix A of this part).
Hydrogen chloride	62 parts per million by dry volume	3-run average (For Method 26, collect a minimum volume of 120 liters per run. For Method 26A, collect a minimum volume of 1 dry standard cubic meter per run).	Performance test (Method 26 or 26A at 40 CFR part 60, appendix A–8).
Lead	0.04 milligrams per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Performance test (Method 29 of appendix A of this part)
Mercury	0.47 milligrams per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Performance test (Method 29 or 30B at 40 CFR part 60, appendix A–8) or ASTM D6784–02 (Reapproved 2008).[3]
Opacity	10 percent	Three 1-hour blocks consisting of ten 6-minute average opacity values.	Performance test (Method 9 at 40 CFR part 60, appendix A–4).
Oxides of nitrogen	388 parts per million by dry volume	3-run average (1 hour minimum sample time per run).	Performance test (Methods 7 or 7E at 40 CFR part 60, appendix A–4).
Particulate matter	70 milligrams per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Performance test (Method 5 or 29 of appendix A of this part).
Sulfur dioxide	20 parts per million by dry volume	3-run average (1 hour minimum sample time per run).	Performance test (Method 6 or 6c of appendix A of this part).

[1] All emission limitations (except for opacity) are measured at 7 percent oxygen, dry basis at standard conditions.

[2] Applies only to incinerators subject to the CISWI standards through a state plan or the Federal plan prior to June 4, 2010. The date specified in the state plan can be no later than 3 years after the effective date of approval of a revised state plan or February 7, 2018.

[3] Incorporated by reference, *see* § 60.17.

Table 3 to Subpart DDDD of Part 60—Model Rule—Operating Limits for Wet Scrubbers

For these operating parameters	You must establish these operating limits	And monitor using these minimum frequencies		
		Data measurement	Data recording	Averaging time
Charge rate	Maximum charge rate	Continuous	Every hour	Daily (batch units). 3-hour rolling (continuous and intermittent units).[1]
Pressure drop across the wet scrubber or amperage to wet scrubber.	Minimum pressure drop or amperage.	Continuous	Every 15 minutes	3-hour rolling.[1]
Scrubber liquor flow rate	Minimum flow rate	Continuous	Every 15 minutes	3-hour rolling.[1]
Scrubber liquor pH	Minimum pH	Continuous	Every 15 minutes	3-hour rolling.[1]

[1] Calculated each hour as the average of the previous 3 operating hours.

Table 4 to Subpart DDDD of Part 60—Model Rule—Toxic Equivalency Factors

Dioxin/furan isomer	Toxic equivalency factor
2,3,7,8-tetrachlorinated dibenzo-p-dioxin	1
1,2,3,7,8-pentachlorinated dibenzo-p-dioxin	0.5
1,2,3,4,7,8-hexachlorinated dibenzo-p-dioxin	0.1
1,2,3,7,8,9-hexachlorinated dibenzo-p-dioxin	0.1
1,2,3,6,7,8-hexachlorinated dibenzo-p-dioxin	0.1
1,2,3,4,6,7,8-heptachlorinated dibenzo-p-dioxin	0.01
octachlorinated dibenzo-p-dioxin	0.001
2,3,7,8-tetrachlorinated dibenzofuran	0.1
2,3,4,7,8-pentachlorinated dibenzofuran	0.5
1,2,3,7,8-pentachlorinated dibenzofuran	0.05
1,2,3,4,7,8-hexachlorinated dibenzofuran	0.1
1,2,3,6,7,8-hexachlorinated dibenzofuran	0.1
1,2,3,7,8,9-hexachlorinated dibenzofuran	0.1
2,3,4,6,7,8-hexachlorinated dibenzofuran	0.1
1,2,3,4,6,7,8-heptachlorinated dibenzofuran	0.01
1,2,3,4,7,8,9-heptachlorinated dibenzofuran	0.01
octachlorinated dibenzofuran	0.001

Table 5 to Subpart DDDD of Part 60—Model Rule—Summary of Reporting Requirements [1]

Report	Due date	Contents	Reference
Waste Management Plan	No later than the date specified in table 1 for submittal of the final control plan.	• Waste management plan	§ 60.2755.
Initial Test Report	No later than 60 days following the initial performance test.	• Complete test report for the initial performance test. • The values for the site-specific operating limits. • Installation of bag leak detection systems for fabric filters.	§ 60.2760.
Annual report	No later than 12 months following the submission of the initial test report. Subsequent reports are to be submitted no more than 12 months following the previous report. • Statement and signature by responsible official • Date of report • Values for the operating limits • Highest recorded 3-hour average and the lowest 3-hour average, as applicable, for each operating parameter recorded for the calendar year being reported. • If a performance test was conducted during the reporting period, the results of the test. • If a performance test was not conducted during the reporting period, a statement that the requirements of § 60.2720(a) were met. • Documentation of periods when all qualified CISWI unit operators were unavailable for more than 8 hours but less than 2 weeks. • If you are conducting performance tests once every 3 years consistent with § 60.2720(a), the date of the last 2 performance tests, a comparison of the emission level you achieved in the last 2 performance tests to the 75 percent emission limit threshold required in § 60.2720(a) and a statement as to whether there have been any operational changes since the last performance test that could increase emissions.	• Name and address	§§ 60.2765 and 60.2770.

TABLE 5 TO SUBPART DDDD OF PART 60—MODEL RULE—SUMMARY OF REPORTING REQUIREMENTS [1]—Continued

Report	Due date	Contents	Reference
Emission limitation or operating limit deviation report.	By August 1 of that year for data collected during the first half of the calendar year. By February 1 of the following year for data collected during the second half of the calendar year.	• Dates and times of deviation • Averaged and recorded data for those dates. • Duration and causes of each deviation and the corrective actions taken. • Copy of operating limit monitoring data and any test reports. • Dates, times and causes for monitor downtime incidents.	§ 60.2775 and 60.2780.
Qualified Operator Deviation Notification.	Within 10 days of deviation	• Statement of cause of deviation • Description of efforts to have an accessible qualified operator. • The date a qualified operator will be accessible.	§ 60.2785(a)(1).
Qualified Operator Deviation Status Report.	Every 4 weeks following deviation	• Description of efforts to have an accessible qualified operator. • The date a qualified operator will be accessible. • Request for approval to continue operation.	§ 60.2785(a)(2).
Qualified Operator Deviation Notification of Resumed Operation.	Prior to resuming operation	• Notification that you are resuming operation.	§ 60.2785(b)

[1] This table is only a summary, see the referenced sections of the rule for the complete requirements.

TABLE 6 TO SUBPART DDDD OF PART 60—MODEL RULE—EMISSION LIMITATIONS THAT APPLY TO INCINERATORS ON AND AFTER

[Date to be specified in state plan] [1]

For the air pollutant	You must meet this emission limitation [2]	Using this averaging time	And determining compliance using this method
Cadmium	0.0026 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 2 dry standard cubic meters).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Carbon monoxide	17 parts per million dry volume	3-run average (1 hour minimum sample time per run).	Performance test (Method 10 at 40 CFR part 60, appendix A–4).
Dioxins/furans (total mass basis).	4.6 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 2 dry standard cubic meters).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Dioxins/furans (toxic equivalency basis).	0.13 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 2 dry standard cubic meters).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Hydrogen chloride	29 parts per million dry volume	3-run average (For Method 26, collect a minimum volume of 60 liters per run. For Method 26A, collect a minimum volume of 1 dry standard cubic meter per run).	Performance test (Method 26 or 26A at 40 CFR part 60, appendix A–8).
Lead	0.015 milligrams per dry standard cubic meter [3].	3-run average (collect a minimum volume of 2 dry standard cubic meters).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Mercury	0.0048 milligrams per dry standard cubic meter.	3-run average (For Method 29 an ASTM D6784–02 (Reapproved 2008) [4], collect a minimum volume of 2 dry standard cubic meters per run. For Method 30B, collect a minimum sample as specified in Method 30B at 40 CFR part 60, appendix A).	Performance test (Method 29 or 30B at 40 CFR part 60, appendix A–8) or ASTM D6784–02 (Reapproved 2008). [4]
Oxides of nitrogen	53 parts per million dry volume	3-run average (for Method 7E, 1 hour minimum sample time per run).	Performance test (Method 7 or 7E at 40 CFR part 60, appendix A–4).
Particulate matter filterable.	34 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meter).	Performance test (Method 5 or 29 at 40 CFR part 60, appendix A–3 or appendix A–8).
Sulfur dioxide	11 parts per million dry volume	3-run average (1 hour minimum sample time per run).	Performance test (Method 6 or 6c at 40 CFR part 60, appendix A–4).

TABLE 6 TO SUBPART DDDD OF PART 60—MODEL RULE—EMISSION LIMITATIONS THAT APPLY TO INCINERATORS ON AND AFTER—Continued

[Date to be specified in state plan][1]

For the air pollutant	You must meet this emission limitation[2]	Using this averaging time	And determining compliance using this method
Fugitive ash	Visible emissions for no more than 5% of the hourly observation period.	Three 1-hour observation periods	Visible emission test (Method 22 at 40 CFR part 60, appendix A–7).

[1] The date specified in the state plan can be no later than 3 years after the effective date of approval of a revised state plan or February 7, 2018.

[2] All emission limitations are measured at 7 percent oxygen, dry basis at standard conditions. For dioxins/furans, you must meet either the total mass basis limit or the toxic equivalency basis limit.

[3] If you are conducting stack tests to demonstrate compliance and your performance tests for this pollutant for at least 2 consecutive years show that your emissions are at or below this limit, you can skip testing according to § 60.2720 if all of the other provisions of § 60.2720 are met. For all other pollutants that do not contain a footnote "3", your performance tests for this pollutant for at least 2 consecutive years must show that your emissions are at or below 75 percent of this limit in order to qualify for skip testing.

[4] Incorporated by reference, see § 60.17.

TABLE 7 TO SUBPART DDDD OF PART 60—MODEL RULE—EMISSION LIMITATIONS THAT APPLY TO ENERGY RECOVERY UNITS AFTER MAY 20, 2011

[Date to be specified in state plan][1]

For the air pollutant	You must meet this emission limitation[2]		Using this averaging time	And determining compliance using this method
	Liquid/Gas	Solids		
Cadmium	0.023 milligrams per dry standard cubic meter.	Biomass—0.0014 milligrams per dry standard cubic meter. Coal—0.0017 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 2 dry standard cubic meters).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Carbon monoxide	35 parts per million dry volume.	Biomass—260 parts per million dry volume. Coal—95 parts per million dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 10 at 40 CFR part 60, appendix A–4).
Dioxins/furans (total mass basis).	2.9 nanograms per dry standard cubic meter.	Biomass—0.52 nanograms per dry standard cubic meter.[3] Coal—5.1 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meter).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Dioxins/furans (toxic equivalency basis).	0.32 nanograms per dry standard cubic meter.	Biomass—0.12 nanograms per dry standard cubic meter. Coal—0.075 nanograms per dry standard cubic meter[3].	3-run average (collect a minimum volume of 4 dry standard cubic meters).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Hydrogen chloride	14 parts per million dry volume.	Biomass—0.20 parts per million dry volume. Coal—58 parts per million dry volume.	3-run average (for Method 26, collect a minimum of 120 liters; for Method 26A, collect a minimum volume of 1 dry standard cubic meter).	Performance test (Method 26 or 26A at 40 CFR part 60, appendix A–8).
Lead	0.096 milligrams per dry standard cubic meter.	Biomass—0.014 milligrams per dry standard cubic meter.[3] Coal—0.057 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 2 dry standard cubic meters).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Mercury	0.0024 milligrams per dry standard cubic meter.	Biomass—0.0022 milligrams per dry standard cubic meter. Coal—0.013 milligrams per dry standard cubic meter.	3-run average (For Method 29 and ASTM D6784–02 (Reapproved 2008),[4] collect a minimum volume of 2 dry standard cubic meters per run. For Method 30B, collect a minimum sample as specified in Method 30B at 40 CFR part 60, appendix A).	Performance test (Method 29 or 30B at 40 CFR part 60, appendix A–8) or ASTM D6784–02 (Reapproved 2008).[4]
Oxides of nitrogen	76 parts per million dry volume.	Biomass—290 parts per million dry volume. Coal—460 parts per million dry volume.	3-run average (for Method 7E, 1 hour minimum sample time per run).	Performance test (Method 7 or 7E at 40 CFR part 60, appendix A–4).

TABLE 7 TO SUBPART DDDD OF PART 60—MODEL RULE—EMISSION LIMITATIONS THAT APPLY TO ENERGY RECOVERY UNITS AFTER MAY 20, 2011—Continued

[Date to be specified in state plan][1]

For the air pollutant	You must meet this emission limitation[2]		Using this averaging time	And determining compliance using this method
	Liquid/Gas	Solids		
Particulate matter filterable.	110 milligrams per dry standard cubic meter.	Biomass—11 milligrams per dry standard cubic meter. Coal—130 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meter).	Performance test (Method 5 or 29 at 40 CFR part 60, appendix A–3 or appendix A–8) if the unit has an annual average heat input rate less than or equal to 250 MMBtu/hr; or PM CPMS (as specified in § 60.2710(x)) if the unit has an annual average heat input rate greater than 250 MMBtu/hr.
Sulfur dioxide	720 parts per million dry volume.	Biomass—7.3 parts per million dry volume. Coal—850 parts per million dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 6 or 6c at 40 CFR part 60, appendix A–4).
Fugitive ash	Visible emissions for no more than 5 percent of the hourly observation period.	Visible emissions for no more than 5 percent of the hourly observation period.	Three 1-hour observation periods.	Visible emission test (Method 22 at 40 CFR part 60, appendix A–7).

[1] The date specified in the state plan can be no later than 3 years after the effective date of approval of a revised state plan or February 7, 2018.

[2] All emission limitations (except for opacity) are measured at 7 percent oxygen, dry basis at standard conditions. For dioxins/furans, you must meet either the total mass basis limit or the toxic equivalency basis limit.

[3] If you are conducting stack tests to demonstrate compliance and your performance tests for this pollutant for at least 2 consecutive years show that your emissions are at or below this limit, you can skip testing according to § 60.2720 if all of the other provisions of § 60.2720 are met. For all other pollutants that do not contain a footnote "3", your performance tests for this pollutant for at least 2 consecutive years must show that your emissions are at or below 75 percent of this limit in order to qualify for skip testing, with the exception of annual performance tests to certify a CEMS or PM CPMS.

[4] Incorporated by reference, see § 60.17.

TABLE 8 TO SUBPART DDDD OF PART 60—MODEL RULE—EMISSION LIMITATIONS THAT APPLY TO WASTE-BURNING KILNS AFTER MAY 20, 2011

[Date to be specified in state plan.][1]

For the air pollutant	You must meet this emission limitation[2]	Using this averaging time	And determining compliance using this method[4]
Cadmium	0.0014 milligrams per dry standard cubic meter[3].	3-run average (collect a minimum volume of 2 dry standard cubic meters).	Performance test (Method 29 at 40 CFR part 60, appendix A–8).
Carbon monoxide	110 (long kilns)/790 (preheater/precalciner) parts per million dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 10 at 40 CFR part 60, appendix A–4).
Dioxins/furans (total mass basis).	1.3 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meters).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Dioxins/furans (toxic equivalency basis).	0.075 nanograms per dry standard cubic meter[3].	3-run average (collect a minimum volume of 4 dry standard cubic meters).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Hydrogen chloride	3.0 parts per million dry volume[3].	3-run average (collect a minimum volume of 1 dry standard cubic meter) or 30-day rolling average if HCl CEMS is being used.	Performance test (Method 321 at 40 CFR part 63, appendix A of this part) or HCl CEMS if a wet scrubber or dry scrubber is not used, as specified in § 60.2710(j).
Lead	0.014 milligrams per dry standard cubic meter[3].	3-run average (collect a minimum volume of 2 dry standard cubic meters).	Performance test (Method 29 at 40 CFR part 60, appendix A–8).
Mercury	0.011 milligrams per dry standard cubic meter.	30-day rolling average	Mercury CEMS or sorbent trap monitoring system (performance specification 12A or 12B, respectively, of appendix B of this part), as specified in § 60.2710(j).
Oxides of nitrogen	630 parts per million dry volume.	3-run average (for Method 7E, 1 hour minimum sample time per run).	Performance test (Method 7 or 7E at 40 CFR part 60, appendix A–4).
Particulate matter filterable.	13.5 milligrams per dry standard cubic meter.	30-day rolling average	PM CPMS (as specified in § 60.2710(x)).

TABLE 8 TO SUBPART DDDD OF PART 60—MODEL RULE—EMISSION LIMITATIONS THAT APPLY TO WASTE-BURNING KILNS AFTER MAY 20, 2011—Continued

[Date to be specified in state plan.] [1]

For the air pollutant	You must meet this emission limitation [2]	Using this averaging time	And determining compliance using this method [4]
Sulfur dioxide	600 parts per million dry volume.	3-run average (for Method 6, collect a minimum of 20 liters; for Method 6C, 1 hour minimum sample time per run).	Performance test (Method 6 or 6c at 40 CFR part 60, appendix A–4).

[1] The date specified in the state plan can be no later than 3 years after the effective date of approval of a revised state plan or February 7, 2018.

[2] All emission limitations are measured at 7 percent oxygen (except for CEMS data during startup and shutdown), dry basis at standard conditions. For dioxins/furans, you must meet either the total mass basis limit or the toxic equivalency basis limit.

[3] If you are conducting stack tests to demonstrate compliance and your performance tests for this pollutant for at least 2 consecutive years show that your emissions are at or below this limit, you can skip testing according to § 60.2720 if all of the other provisions of § 60.2720 are met. For all other pollutants that do not contain a footnote "3", your performance tests for this pollutant for at least 2 consecutive years must show that your emissions are at or below 75 percent of this limit in order to qualify for skip testing, with the exception of annual performance tests to certify a CEMS or PM CPMS.

[4] Alkali bypass and in-line coal mill stacks are subject to performance testing only, as specified in 60.2710(y)(3). They are not be subject to the CEMS, sorbent trap or CPMS requirements that otherwise may apply to the main kiln exhaust.

TABLE 9 TO SUBPART DDDD OF PART 60—MODEL RULE—EMISSION LIMITATIONS THAT APPLY TO SMALL, REMOTE INCINERATORS AFTER MAY 20, 2011

[Date to be specified in state plan] [1]

For the air pollutant	You must meet this emission limitation [2]	Using this averaging time	And determining compliance using this method
Cadmium	0.95 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters per run).	Performance test (Method 29 at 40 CFR part 60, appendix A–8).
Carbon monoxide	64 parts per million dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 10 at 40 CFR part 60, appendix A–4).
Dioxins/furans (total mass basis).	4,400 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters per run).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Dioxins/furans (toxic equivalency basis).	180 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Fugitive ash	Visible emissions for no more than 5 percent of the hourly observation period.	Three 1-hour observation periods	Visible emissions test (Method 22 at 40 CFR part 60, appendix A–7).
Hydrogen chloride	300 parts per million dry volume.	3-run average (For Method 26, collect a minimum volume of 120 liters per run. For Method 26A, collect a minimum volume of 1 dry standard cubic meter per run).	Performance test (Method 26 or 26A at 40 CFR part 60, appendix A–8).
Lead	2.1 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Mercury	0.0053 milligrams per dry standard cubic meter.	3-run average (For Method 29 and ASTM D6784–02 (Reapproved 2008),[3] collect a minimum volume of 2 dry standard cubic meters per run. For Method 30B, collect a minimum sample as specified in Method 30B at 40 CFR part 60, appendix A).	Performance test (Method 29 or 30B at 40 CFR part 60, appendix A–8) or ASTM D6784–02 (Reapproved 2008).[3]
Oxides of nitrogen	190 parts per million dry volume.	3-run average (for Method 7E, 1 hour minimum sample time per run).	Performance test (Method 7 or 7E at 40 CFR part 60, appendix A–4).
Particulate matter (filterable)	270 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters).	Performance test (Method 5 or 29 at 40 CFR part 60, appendix A–3 or appendix A–8).
Sulfur dioxide	150 parts per million dry volume.	3-run average (for Method 6, collect a minimum of 20 liters per run; for Method 6C, 1 hour minimum sample time per run).	Performance test (Method 6 or 6c at 40 CFR part 60, appendix A–4).

[1] The date specified in the state plan can be no later than 3 years after the effective date of approval of a revised state plan or February 7, 2018.

[2] All emission limitations (except for opacity) are measured at 7 percent oxygen, dry basis at standard conditions. For dioxins/furans, you must meet either the total mass basis limit or the toxic equivalency basis limit.

[3] Incorporated by reference, see § 60.17.

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 414
Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1621–F]

RIN 0938–AS33

Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements requirements of section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), which significantly revises the Medicare payment system for clinical diagnostic laboratory tests. This final rule also announces an implementation date of January 1, 2018 for the private payor rate-based fee schedule required by PAMA.

DATES: These regulations are effective on August 22, 2016.

FOR FURTHER INFORMATION CONTACT: Marie Casey, (410) 786–7861 or Karen Reinhardt (410) 786–0189 for issues related to the local coverage determination process for clinical diagnostic laboratory tests. Valerie Miller, (410) 786–4535 or Sarah Harding, (410) 786–4001 for all other issues.

SUPPLEMENTARY INFORMATION: To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

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Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing these abbreviations and their corresponding terms in alphabetical order below:

ADLT	Advanced Diagnostic Laboratory Test
CCN	CMS Certification Number
CDLT	Clinical Diagnostic Laboratory Test
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CLFS	Clinical Laboratory Fee Schedule
CLIA	Clinical Laboratory Improvement Amendments of 1988
CMP	Civil Monetary Penalty
CMS	Centers for Medicare & Medicaid Services
CPT	American Medical Association's Current Procedural Terminology
CR	Change Request
CY	Calendar Year
DNA	Deoxyribonucleic Acid
FDA	Food and Drug Administration
HCPCS	Healthcare Common Procedure Coding System
HHA	Home Health Agency
HIPAA	Health Insurance Portability and Accountability Act of 1996
IRS	Internal Revenue Service
LCD	Local Coverage Determination
MAC	Medicare Administrative Contractor
NCD	National Coverage Determination
NLA	National Limitation Amount
NOC	Not Otherwise Classified
NPI	National Provider Identifier
OPPS	Hospital Outpatient Prospective Payment System
PAMA	Protecting Access to Medicare Act of 2014
PFS	Physician Fee Schedule
Q1	First Quarter
Q2	Second Quarter
Q3	Third Quarter
Q4	Fourth Quarter
RNA	Ribonucleic Acid
SNF	Skilled Nursing Facility
TIN	Taxpayer Identification Number

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

Since 1984, Medicare has paid for clinical diagnostic laboratory tests (CDLTs) on the Clinical Laboratory Fee Schedule (CLFS) under section 1833(h) of the Social Security Act (the Act). Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted on April 1, 2014) added section 1834A to the Act. The statute requires extensive revisions to the Medicare payment, coding, and coverage requirements for CDLTs, as well as creates a new subcategory of CDLTs called Advanced Diagnostic Laboratory Tests (ADLTs) with separate reporting and payment requirements. In this final rule, we present our policies for implementing the requirements of section 1834A of the Act.

2. Summary of the Major Provisions

Section 1834A of the Act significantly changes how CMS will set Medicare payment rates for CDLTs that are paid for under the CLFS. In general, with certain designated exceptions, the statute requires that the payment amount for CDLTs furnished on or after January 1, 2017, be equal to the weighted median of private payor rates determined for the test, based on certain data reported by laboratories during a specified data collection period. Different reporting and payment requirements will apply to a subset of CDLTs that are determined to be ADLTs. The most significant policies adopted in this final rule include the following (more detailed descriptions follow the bulleted list):

- The implementation date for CLFS rates based on the weighted median of private payor rates.

- The definition of "applicable laboratory".
- The definition of "reporting entity" (the entity that must report applicable information).
- The definition of "applicable information" (the specific data that must be reported).
- The definition of ADLT.
- Data collection and data reporting schedules.
- Data integrity.
- Confidentiality and public release of limited data.
- Coding for certain CDLTs.
- The payment methodology for CDLTs.
- The local coverage determination (LCD) process and the authority to designate Medicare Administrative Contractors (MACs) for clinical diagnostic laboratory tests.

Section 1834A(b)(1)(A) of the Act requires that, for a CDLT furnished on or after January 1, 2017, the amount Medicare pays for the CDLT must be equal to the weighted median of private payor rates for the CDLT. After considering public comments recommending that we revise the implementation date of the CLFS, we have decided to move the implementation date to January 1, 2018. Thus, for a CDLT furnished on or after January 1, 2018, the amount Medicare pays will be equal to the weighted median of private payor rates for the CDLT.

Under the authority of section 1834A(a)(2) of the Act, which requires applicable laboratories to report applicable information to CMS to be used in establishing the new CLFS payment rates, we proposed to define an applicable laboratory as an entity that: (1) Reports tax-related information to the Internal Revenue Service (IRS) under a Taxpayer Identification Number (TIN) with which all of the National Provider Identifiers (NPIs) in the entity are associated; (2) is itself a laboratory, as defined in § 493.2, or, if it is not itself a laboratory, has at least one component that is a laboratory, as defined in § 493.2, for which the entity reports tax-related information to the IRS using its TIN; (3) in a data collection period, receives, collectively with its associated NPI entities, more than 50 percent of its Medicare revenues from the CLFS or Physician Fee Schedule (PFS); (4) for the data collection period from July 1, 2015 through December 31, 2015, receives, collectively with its associated NPI entities, at least $25,000 of its Medicare revenues from the CLFS; and (5) for all subsequent data collection periods receives, collectively with its associated NPI entities, at least $50,000 of its Medicare revenues from the CLFS.

After considering the comments we received, we are retaining some aspects of the proposed definition and revising others. In this final rule, the applicable laboratory is defined at the NPI level, rather than the TIN level, so we have removed the pieces of the definition that refer to the TIN-level entity. However, we are retaining the TIN-level entity as the "reporting entity" (now defined separately from the applicable laboratory), which is responsible for reporting applicable information for all of its component NPI-level entities that meet the definition of applicable laboratory. We are retaining the "majority of Medicare revenues" threshold, but it will be applied to the NPI-level entity, rather than the TIN-level entity. We are finalizing a low expenditure threshold, but we are revising the amount because the threshold will be applied at the NPI level as opposed to the TIN level and will reflect a 6-month data collection period instead of a full calendar year. Under our final policy, if a laboratory receives less than $12,500 of its Medicare revenues from the CLFS during the data collection period, it is excluded from the definition of applicable laboratory. For a single laboratory that offers and furnishes an ADLT, the $12,500 threshold will not apply with respect to the ADLT. This means, if the laboratory otherwise meets the definition of applicable laboratory, whether or not it meets the low expenditure threshold, it will be considered an applicable laboratory with respect to the ADLT it offers and furnishes, and must report applicable information for its ADLT. If it does not meet the threshold, it will not be considered an applicable laboratory with respect to all the other CDLTs it furnishes.

The statute requires the following applicable information to be reported for each test on the CLFS an applicable laboratory performs: (1) The payment rate that was paid by each private payor for each test during the data collection period; and (2) the volume of such tests for each such payor. We proposed to use the term "private payor rate" in the context of applicable information, instead of "payment rate," to minimize confusion because we typically use the term payment rate to generically refer to the amount paid under the CLFS. We also proposed that the private payor rate reflect the price for a test prior to application of any deductible or coinsurance amounts owed by the patient. In this final rule we are adopting these policies as final. We proposed that only applicable laboratories may report applicable information. We are also finalizing that requirement, but rephrasing it in the regulation to conform to our final policy that reporting entities, rather than applicable laboratories, will be reporting applicable information.

Section 1834A(d)(5) of the Act specifies criteria for defining an ADLT and authorizes the Secretary to establish additional criteria. We proposed to apply the criteria specified in statute, but not any additional criteria under the statutory authority conferred upon the Secretary, and are finalizing that proposal in this final rule. In addition, in the proposed rule, we defined an ADLT, in part, to be a molecular pathology analysis of multiple biomarkers of deoxyribonucleic acid (DNA), or ribonucleic acid (RNA). However, in response to public comments, we are removing the requirement that the test be a molecular pathology analysis and permitting protein-only based tests to also qualify for ADLT status.

We proposed that the initial data collection period would be July 1, 2015, through December 31, 2015, and that all subsequent data collection periods would be a full calendar year, from January 1 through December 31. After consideration of the comments we received, and because we no longer need to implement a shortened time frame for the initial data reporting period in light of our moving the implementation date of the revised CLFS to January 1, 2018, we are adopting the policy that all data collection periods are 6 months long, from January 1 through June 30. Further, we proposed that all applicable information, except applicable information for new ADLTs, would be reported to us in a data reporting period that would begin on January 1 and end on March 31 of the year following the data collection period. We are finalizing this policy in this final rule. However, because we are finalizing that reporting entities, and not applicable laboratories, must report applicable information, we have revised the final data reporting requirements regulation accordingly.

We proposed that the applicable information for new ADLTs must be reported initially to us by the end of the second quarter of the new ADLT initial period, which we are finalizing. We also proposed that the new ADLT initial period would be a period of 3 calendar quarters that begins on the first full calendar quarter following the first day on which a new ADLT is performed. After consideration of public comments, we are revising this policy and requiring, instead, that the data collection period for a new ADLT will begin on the first day of the first full calendar quarter following the latter of either the date a Medicare Part B coverage determination is made or ADLT status is granted by us.

The statute specifies that if, after a new ADLT initial period, the Secretary determines the payment amount that was applicable during the initial period (the test's actual list charge) was greater than 130 percent of the payment amount that is applicable after such period (based on private payor rates), the Secretary shall recoup the difference between those payment amounts for tests furnished during the initial period. We proposed to recoup the entire amount of the difference between the actual list charge and the weighted median private payer rate. After consideration of public comments, we are revising our proposed policy so that, for tests furnished during the new ADLT initial period, we will pay up to 130 percent of the weighted median private payor rate. That is, if the actual list charge is subsequently determined to be greater than 130 percent of the weighted median private payor rate, we will recoup the difference between the actual list charge and 130 percent of the weighted median private payer rate.

We proposed to apply a civil monetary penalty (CMP) to an applicable laboratory that fails to report or that makes a misrepresentation or omission in reporting applicable information. We proposed to require all data to be certified by the President, Chief Executive Officer (CEO), or Chief Financial Officer (CFO) of an applicable laboratory before it is submitted to CMS. As required by section 1834A(a)(10) of the Act, certain information disclosed by a laboratory under section 1834A(a) of the Act is confidential and may not be disclosed by the Secretary or a Medicare contractor in a form that reveals the identity of a specific payor or laboratory, or prices, charges or payments made to any such laboratory, with several exceptions. We are revising the certification and CMP policies in the final rule to require that the accuracy of the data be certified by the President, CEO, or CFO of the reporting entity, or an individual who has been delegated to sign for, and who reports directly to such an officer. Similarly, the reporting entity will be subject to CMPs for the failure to report or the misrepresentation or omission in reporting applicable information. Additionally, we are updating the CMP amount to reflect changes required by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. 114–74, November 2, 2015).

We proposed to use G codes, which are part of the Healthcare Common Procedure Coding System (HCPCS) we use for programmatic purposes, to temporarily identify new ADLTs and new laboratory tests that are cleared or approved by the Food and Drug Administration (FDA). The temporary codes would be in effect for up to 2 years until a permanent HCPCS code is established except if the Secretary determines it is appropriate to extend the use of the temporary code. We are finalizing this policy in this final rule.

As required by section 1834A(b) of the Act, payment amounts for laboratory tests on the CLFS will be determined by calculating a weighted median of private payor rates using reported private payor rates and associated volume (number of tests). For tests that were paid on the CLFS prior to the implementation of section 1834A of the Act, PAMA requires that any reduction in payment amount be phased in over the first 6 years of payment under the new system. For new ADLTs, initial payment will be based on the actual list charge of the test for 3 calendar quarters; thereafter, the payment rate will be determined using the weighted median of private payor rates and associated volume (number of tests) reported every year. For new and existing tests for which we receive no applicable information to calculate a weighted median, we proposed that payment rates be determined by using crosswalking or gapfilling methods. These methods of determining payment were discussed in the proposed rule (80 FR 59404). We are finalizing these policies in this final rule.

Section 1834A(g)(2) of the Act authorizes the Secretary to designate one or more (not to exceed four) MACs to establish coverage policies, or establish coverage policies and process claims, for CDLTs. As noted in section II.I of the proposed rule, we requested public comment on the benefits and disadvantages of implementing this discretionary authority before making proposals on this topic. While we proposed no changes to the CDLT LCD development and implementation processes or claims processing functions in this final rule, our review of the comments received and our response to comments is contained in section II.I below.

3. Summary of Costs and Benefits

In section VI. of this final rule, we provide a regulatory impact analysis that, to the best of our ability, describes the expected impact of the policies we are adopting in this final rule. These policies, which implement section 1834A of the Act, include a process for collecting the applicable information of applicable laboratories for CDLTs. We note that, because such data are not yet available, we are limited in our ability to provide estimated impacts of the payment policies under different scenarios. However, we believe this final rule is an economically significant rule because we believe that the changes to how CLFS payment rates will be developed will overall decrease payments to entities paid under the CLFS. Accordingly, in section IV., we have prepared a Regulatory Impact Analysis that, to the best of our ability, presents the costs and benefits of the rulemaking.

B. Background

1. The Medicare Clinical Laboratory Fee Schedule (CLFS)

Currently, under sections 1832, 1833(a), (b), and (h), and 1861 of the Act, CDLTs furnished on or after July 1, 1984 in a physician's office, by an independent laboratory, or in limited circumstances by a hospital laboratory for its outpatients or non-patients are paid under the Medicare CLFS, with certain exceptions. Under these sections, tests are paid the lesser of (1) the billed amount, (2) the local fee schedule amount established by the Medicare contractor, or (3) a National Limitation Amount (NLA), which is a percentage of the median of all the local fee schedule amounts (or 100 percent of the median for new tests furnished on or after January 1, 2001). In practice, most tests are paid at the NLA.

Under the current system, the CLFS amounts are updated for inflation based on the percentage change in the Consumer Price Index for all urban consumers (CPI–U) and reduced by a multi-factor productivity adjustment (see section 1833(h)(2)(A) of the Act). For CY 2015, under section 1833(h)(2)(A)(iv)(II) of the Act, we also reduced the update amount by 1.75 percentage points. In the past, we have implemented other adjustments or did not apply the change in the CPI–U to the CLFS for certain years in accordance with statutory mandates. We do not otherwise have authority to update or change the payment amounts for tests on the CLFS. Generally, coinsurance and deductibles do not apply to CDLTs paid under the CLFS.

For any CDLT for which a new or substantially revised HCPCS code has been assigned on or after January 1, 2005, we determine the basis for and amount of payment based on one of two methodologies—crosswalking and gapfilling (see section 1833(h)(8) of the Act and §§ 414.500 through 414.509). The crosswalking methodology is used when a new test is comparable in terms of test methods and resources to an existing test code, multiple existing test codes, or a portion of an existing test code on the CLFS. In such a case, we assign the new test code the local fee schedule amount and the NLA of the existing test and pay for the new test code at the lesser of the local fee schedule amount or the NLA. Gapfilling is used when no comparable test exists on the CLFS. Under gapfilling, the MACs establish local payment amounts for the new test code using the following sources of information, if available: (1) Charges for the test and routine discounts to charges; (2) resources required to perform the test; (3) payment amounts determined by other payors; and (4) charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant. Under this gapfilling methodology, an NLA is calculated after a year of payment at the local contractor rates, based on the median of rates for the test code across all MACs. Once an NLA is established, in most cases, we can only reconsider the crosswalking or gapfilling basis and/or amount of payment for new tests for one additional year after the basis or payment is initially set. Once the reconsideration process is complete, payment cannot be further adjusted (except by a change in the CPI–U, the productivity adjustment, and any other adjustments required by statute).

In 2014, Medicare paid approximately $7 billion for CDLTs. As the CLFS has grown from approximately 400 tests to over 1,300 tests, some test methods have become outdated and some tests may no longer be priced appropriately. For example, some tests have become more automated and cheaper to perform, with little need for manual interaction by laboratory technicians, while more expensive and complex tests have been developed that bear little resemblance to the simpler tests that were performed at the inception of the CLFS.

2. Statutory Bases for Changes in Payment, Coding, and Coverage Policies for Clinical Diagnostic Laboratory Tests

Section 1834A of the Act, as added by section 216(a) of PAMA, requires extensive revisions to the Medicare payment, coding, and coverage requirements for CDLTs. In this section, we describe the major provisions of section 1834A of the Act, which we are implementing in this final rule.

Section 1834A(a)(1) of the Act requires reporting of private payor payment rates for CDLTs made to applicable laboratories to establish Medicare payment rates for tests paid under the CLFS. Applicable information must be reported to the Secretary, at a time specified by the Secretary and for a designated data collection period, for each CDLT an applicable laboratory furnishes during such period for which Medicare payment is made. Section 1834A(a)(2) of the Act defines the term "applicable laboratory" to mean a laboratory that receives a majority of its Medicare revenues from sections 1834A or 1833(h) of the Act (the statutory authorities under which CLFS payments are or will be made), or section 1848 of the Act (the authority under which PFS payments are made). Section 1834A(a)(2) of the Act also provides that the Secretary may establish a low volume or low expenditure threshold for excluding a laboratory from the definition of an applicable laboratory, as the Secretary determines to be appropriate.

Section 1834A(a)(3)(A) of the Act defines the term "applicable information" as the payment rate that was paid by each private payor for each CDLT and the volume of such tests for each such payor for the data collection period. Under section 1834A(a)(5) of the Act, the payment rate reported by a laboratory must reflect all discounts, rebates, coupons, and other price concessions, including those described in section 1847A(c)(3) of the Act regarding the average sales price for Part B drugs or biologicals. Section 1834A(a)(6) of the Act further specifies that, where an applicable laboratory has more than one payment rate for the same payor for the same test, or more than one payment rate for different payors for the same test, each such payment rate and the volume for the test at each such rate must be reported. The paragraph also provides that, beginning January 1, 2019, the Secretary may establish rules to aggregate reporting in situations where a laboratory has more than one payment rate for the same payor for the same test, or more than one payment rate for different payors for the same test. Under section 1834A(a)(3)(B) of the Act, information about laboratory tests for which payment is made on a capitated basis or other similar payment basis is not considered "applicable information" and is therefore excluded from the reporting requirements.

Section 1834A(a)(4) of the Act defines the term "data collection period" as a period of time, such as a previous 12-month period, specified by the Secretary. Section 1834A(a)(7) of the Act requires that an officer of each laboratory must certify the accuracy and completeness of the applicable information reported. Section 1834A(a)(8) of the Act defines the term "private payor" as a health insurance issuer and a group health plan (as such terms are defined in section 2791 of the Public Health Service Act), a Medicare Advantage plan under Medicare Part C, or a Medicaid managed care organization (as defined in section 1903(m) of the Act).

Section 1834A(a)(9)(A) of the Act authorizes the Secretary to apply a CMP in cases where the Secretary determines that an applicable laboratory has failed to report, or made a misrepresentation or omission in reporting, applicable information under section 1834A(a) of the Act for a CDLT. In these cases, the Secretary may apply a CMP in an amount of up to $10,000 per day for each failure to report or each such misrepresentation or omission. Section 1834A(a)(9)(B) of the Act further provides that the provisions of section 1128A of the Act (other than subsections (a) and (b)) shall apply to a CMP under this paragraph in the same manner as they apply to a CMP or proceeding under section 1128A(a) of the Act. Section 1128A of the Act governs CMPs that apply in general under federal health care programs. Thus, the provisions of section 1128A of the Act (specifically sections 1128A(c) through 1128A(n) of the Act) apply to a CMP under section 1834A(a)(9) of the Act in the same manner as they apply to a CMP or proceeding under section 1128A(a) of the Act. That is, the existing CMP provisions apply to the laboratory data collection process under 1834A of the Act, just as the CMP provisions are applied now to other processes, such as the Medicare Part B and Medicaid drug data collection processes under sections 1847A and 1927 of the Act.

Section 1834A(a)(10) of the Act addresses the confidentiality of the information reported to the Secretary. Specifically, the paragraph provides that, notwithstanding any other provision of law, information disclosed under the data reporting requirements is confidential and shall not be disclosed by the Secretary or a Medicare contractor in a form that discloses the identity of a specific payor or laboratory, or prices charged, or payments made to any such laboratory, except: (1) As the Secretary determines to be necessary to carry out this section; (2) to permit the Comptroller General to review the information provided; (3) to permit the Director of the Congressional Budget Office to review the information provided; and (4) to permit the Medicare Payment Advisory Commission (MedPAC) to review the information provided. Section 1834A(a)(11) of the Act further states that a payor shall not be identified on information reported under the data reporting requirements, and that the name of an applicable laboratory shall be exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552(b)(3).

Section 1834A(a)(12) of the Act requires the Secretary to establish parameters for the data collection under section 1834A(a) of the Act through notice and comment rulemaking no later than June 30, 2015.

Section 1834A(b) of the Act establishes a new methodology for determining Medicare payment rates for CDLTs. Section 1834A(b)(1)(A) of the Act provides that, in general, the payment amount for a CDLT (except for new ADLTs and new CDLTs) furnished on or after January 1, 2017, shall be equal to the weighted median determined under section 1834A(b)(2) of the Act for the test for the most recent data collection period. Section 1834A(b)(1)(B) of the Act specifies that the payment amounts established under this methodology shall apply to a CDLT furnished by a hospital laboratory if the test is paid for separately, and not as part of a bundled payment under the hospital outpatient prospective payment system (OPPS) (section 1833(t) of the Act). Section 1834A(b)(2) of the Act provides that the Secretary shall calculate a weighted median for each test for the data collection period by arraying the distribution of all payment rates reported for the period for each test weighted by volume for each payor and each laboratory. Section 1834A(b)(4)(A) of the Act states that the payment amounts established under this methodology for a year following a data collection period shall continue to apply until the year following the next data collection period. Moreover, section 1834A(b)(4)(B) of the Act specifies that the payment amounts established under section 1834A of the Act shall not be subject to any adjustment (including any geographic adjustment, budget neutrality adjustment, annual update, or other adjustment).

Section 1834A(b)(3) of the Act requires a phase-in of any reduction in payment amounts for a CDLT for each year from 2017 through 2022. Specifically, section 1834A(b)(3)(A) of the Act requires that the payment amounts determined under the new methodology for a CDLT for each of 2017 through 2022 shall not result in a reduction in payments for that test for the year that is greater than the "applicable percent" of the payment amount for the test for the preceding year. Section 1834A(b)(3)(B) of the Act defines these maximum applicable percent reductions as follows: For each of 2017 through 2019, 10 percent; and for each of 2020 through 2022, 15 percent. However, section 1834A(b)(3)(C) of the Act specifies that this payment reduction limit shall not apply to a new CDLT under section 1834A(c)(1) of the Act, or to a new ADLT, as defined in section 1834A(d)(5) of the Act.

Section 1834A(b)(5) of the Act increases by $2 the nominal fee that would otherwise apply under section 1833(h)(3)(A) of the Act for a sample collected from an individual in a Skilled Nursing Facility (SNF) or by a laboratory on behalf of a Home Health Agency (HHA). This provision has the effect of raising the sample collection fee from $3 to $5 when the sample is being collected from an individual in a SNF or by a laboratory on behalf of an HHA.

Section 1834A(d)(5) of the Act defines an ADLT to mean a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and meets one of the following criteria: (1) The test is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins combined with a unique algorithm to yield a single patient-specific result; (2) the test is cleared or approved by the FDA; or (3) the test meets other similar criteria established by the Secretary.

Section 1834A(d)(1)(A) of the Act provides that, in the case of an ADLT for which payment has not been made under the CLFS prior to April 1, 2014 (PAMA's enactment date), during an initial 3 quarters, the payment amount for the test shall be based on the actual list charge for the test. Section 1834A(d)(1)(B) of the Act defines the term "actual list charge" for purposes of this provision to mean the publicly available rate on the first day at which the test is available for purchase by a private payor. For the reporting requirements for such tests, under section 1834A(d)(2) of the Act, an applicable laboratory will initially be required to comply with the data reporting requirements under section 1834A(a) of the Act by the last day of the second quarter (Q2) of the initial 3 quarter period. Section 1834A(d)(3) of the Act requires that, after this initial period, the data reported under paragraph 1834A(d)(2) of the Act shall be used to establish the payment amount for an ADLT described in section 1834A(d)(1)(A) of the Act using the payment methodology for CDLTs under section 1834A(b) of the Act. This payment amount shall continue to apply until the year following the next data collection period.

Section 1834A(d)(4) of the Act addresses recoupment of payment for new ADLTs if the actual list charge exceeds the subsequently established payment amount based on market rates. Specifically, it provides that, if the Secretary determines after the initial period that the payment amount for a new ADLT based on the actual list charge was greater than 130 percent of the payment rate that is calculated using the payment methodology for CDLTs under section 1834A(b) of the Act, the Secretary shall recoup the difference for tests furnished during that initial period.

Section 1834A(c) of the Act provides for payment of new tests that are not ADLTs. Specifically, section 1834A(c)(1) of the Act provides that, in the case of a CDLT that is assigned a new or substantially revised HCPCS code on or after April 1, 2014 (PAMA's enactment date), and which is not an ADLT (as defined in section 1834A(d)(5) of the Act), during an initial period until payment rates under section 1834A(b) of the Act are established for the test, payment for the test shall be determined on the basis of crosswalking or gapfilling. Section 1834A(c)(1)(A) of the Act requires application of the crosswalking methodology described in § 414.508(a) (or any successor regulation) to the most appropriate existing test under the CLFS during that period. Section 1834A(c)(1)(B) of the Act provides that, if no existing test is comparable to the new test, the gapfilling process described in section 1834A(c)(2) of the Act shall be applied. Section 1834A(c)(2) of the Act states that this gapfilling process must take into account the following sources of information to determine gapfill amounts, if available: charges for the test and routine discounts to charges; resources required to perform the test; payment amounts determined by other payors; charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant; and other criteria the Secretary determines to be appropriate. Section 1834A(c)(3) of the Act further requires that, in determining the payment amount under crosswalking or gapfilling processes, the Secretary must consider recommendations from the panel established under section 1834A(f)(1) of the Act. In addition, section 1834A(c)(4) of the Act provides that, in the case of a new CDLT that is not an ADLT, the Secretary shall make available to the public an explanation of the payment rate for the new test, including an explanation of how the gapfilling criteria and panel recommendations described in paragraphs (2) and (3) of section 1834A(c) of the Act are applied.

Section 1834A(e) of the Act sets out coding requirements for certain new and existing tests. Specifically, section 1834A(e)(1)(A) of the Act requires the Secretary to adopt temporary HCPCS codes to identify new ADLTs (as defined in section 1834A(d)(5) of the Act) and new laboratory tests that are cleared or approved by the FDA. Section 1834A(e)(1)(B) of the Act addresses the duration of these temporary new codes. Section 1834A(e)(1)(B)(i) of the Act requires the temporary code to be effective until a permanent HCPCS code is established (but not to exceed 2 years), subject to an exception under section 1834A(e)(1)(B)(ii) of the Act that permits the Secretary to extend the temporary code or establish a permanent HCPCS code, as the Secretary determines appropriate.

Section 1834A(e)(2) of the Act addresses coding for certain existing tests. This section requires that, not later than January 1, 2016, the Secretary shall assign a unique HCPCS code and publicly report the payment rate for each existing ADLT (as defined in section 1834A(d)(5) of the Act) and each existing CDLT that is cleared or approved by the FDA for which payment is made under Medicare Part B as of April 1, 2014 (PAMA's enactment date), if such test has not already been assigned a unique HCPCS code. In addition, section 1834A(e)(3) of the Act requires the establishment of unique identifiers for certain tests. Specifically, for purposes of tracking and monitoring, if a laboratory or a manufacturer requests a unique identifier for an ADLT or a laboratory test that is cleared or approved by the FDA, the Secretary shall use a means to uniquely track such test through a mechanism such as a HCPCS code or modifier.

Section 1834A(f) of the Act addresses requirements for input from clinicians and technical experts on issues related to CDLTs. In particular, section 1834A(f)(1) of the Act requires the Secretary to consult with an expert outside advisory panel that is to be established by the Secretary no later than July 1, 2015. This advisory panel must include an appropriate selection of individuals with expertise, which may include molecular pathologists, researchers, and individuals with expertise in clinical laboratory science or health economics, or in issues related to CDLTs, which may include the development, validation, performance, and application of such tests. Under section 1834A(f)(1)(A) of the Act, this advisory panel is required to provide input on the establishment of payment rates under section 1834A of the Act for new CDLTs, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test, and the factors to be used in determining coverage and payment processes for new CDLTs. Section 1834A(f)(1)(B) of the Act states that the panel may provide recommendations to the Secretary under section 1834A of the Act. Section 1834A(f)(2) of the Act requires the panel to comply with the requirements of the Federal Advisory Committee Act (5 U.S.C. App.). A notice announcing the establishment of the Advisory Panel on CDLTs and soliciting nominations for members was published in the October 27, 2014 **Federal Register** (79 FR 63919 through 63920). The panel's first public meeting was held on August 26, 2015. Information regarding the Advisory Panel on CDLTs is available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.*

Section 1834A(f)(3) of the Act requires that the Secretary continue to convene the annual meeting described in section 1833(h)(8)(B)(iii) of the Act after the implementation of section 1834A of the Act, for purposes of receiving comments and recommendations (and data on which the recommendations are based) on the establishment of payment amounts under section 1834A of the Act.

Section 1834A(g) of the Act addresses issues related to coverage of CDLTs. Section 1834A(g)(1)(A) of the Act requires that coverage policies for CDLTs, when issued by a MAC, be issued in accordance with the LCD process, which we have outlined in Chapter 13 of the Medicare Program Integrity Manual.

In addition, section 1834A(g)(1)(A) of the Act states that the processes governing the appeal and review of CDLT-related LCDs shall continue to follow the general rules for LCD review established by CMS in regulations at 42 CFR part 426.

Section 1834A(g)(1)(B) of the Act states that the CDLT-related LCD provisions referenced in section 1834A(g) of the Act do not apply to the national coverage determination (NCD) process (as defined in section 1869(f)(1)(B) of the Act). Section 1834A(g)(1)(C) of the Act specifies that the provisions pertaining to the LCD process for CDLTs, including appeals of LCDs, shall apply to coverage policies issued on or after January 1, 2015.

In addition, section 1834A(g)(2) of the Act authorizes the Secretary to designate one or more (not to exceed four) MACs to either establish LCDs for CDLTs, or to both establish CDLT-related LCDs and process Medicare claims for payment for CDLTs, as determined appropriate by the Secretary.

Section 1834A(h)(1) of the Act states that there shall be no administrative or judicial review under sections 1869, 1878, or otherwise, of the establishment of payment amounts under section 1834A of the Act. Section 1834A(h)(2) of the Act provides that the Paperwork Reduction Act in chapter 35 of title 44 of the U.S.C. shall not apply to information collected under section 1834A of the Act.

Section 1834A(i) of the Act states that during the period beginning on the date of enactment of section 1834A of the Act (April 1, 2014) and ending on December 31, 2016, the Secretary shall use the methodologies for pricing, coding, and coverage for ADLTs in effect on the day before this period. This may include crosswalking or gapfilling methods.

II. Provisions of the Proposed Regulations and Responses to Public Comments

We received approximately 1,300 public comments from individuals, health care providers, corporations, government agencies, trade associations, and major laboratory organizations. The following are the proposed provisions, a summary of the public comments we received related to each proposal, and our responses to the comments.

A. Definition of Applicable Laboratory

Section 1834A(a)(1) of the Act requires an "applicable laboratory" to report applicable information for a data collection period for each CDLT the laboratory furnishes during the period for which payment is made under Medicare Part B. The statute requires reporting to begin January 1, 2016, and to take place every 3 years thereafter for CDLTs, and every year thereafter for ADLTs. Section 1834A(a)(2) of the Act defines an applicable laboratory as a laboratory that receives a majority of its Medicare revenues from section 1834A and section 1833(h) (the statutory authorities for the CLFS) or section 1848 (the statutory authority for the PFS) of the Act. Section 1834A(a)(2) of the Act also allows the Secretary to establish a low volume or low expenditure threshold for excluding a laboratory from the definition of an applicable laboratory, as the Secretary determines appropriate.

In establishing a regulatory definition for "applicable laboratory," we considered the following issues: (1) How to define "laboratory;" (2) what it means to receive a majority of Medicare revenues from sections 1834A, 1833(h), or 1848 of the Act; (3) how to apply the majority of Medicare revenues criterion; and (4) whether to establish a low volume or low expenditure threshold to exclude an entity from the definition of applicable laboratory.

First, we considered what a laboratory is, and we incorporated our understanding of that term in our proposed definition of applicable laboratory. The CLFS applies to a wide variety of laboratories (for example, national chains, physician offices, hospital laboratories, etc.), and we believed it was important that we define laboratory broadly enough to encompass every laboratory type that is subject to the CLFS.

We searched for existing statutory definitions of "laboratory" that could be appropriate to use for the revised CLFS. However, section 1834A of the Act does not define laboratory, nor is it defined elsewhere in the Medicare statute. So we looked to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for a definition. CLIA applies to all laboratories performing testing on human specimens for a health purpose, including but not limited to those seeking payment under the Medicare and Medicaid programs (§ 493.1). To be paid under Medicare, a laboratory must be CLIA-certified (§ 410.32(d) and part 493). Therefore, we believed it was appropriate to use the CLIA definition of laboratory at § 493.2 for our purposes of defining laboratory within the term applicable laboratory. We did not consider alternative definitions of laboratory as we were not able to identify alternative definitions that would be appropriate for consideration under section 1834A of the Act.

CLIA defines a laboratory as a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both), or only serving as a mailing service and not performing testing, are not considered laboratories, which we believed was also appropriate for our purposes. The services of those facilities that only collect or prepare specimens or serve as a mailing service are not paid on the CLFS. We proposed to incorporate the CLIA regulatory definition of laboratory into our proposed definition of applicable laboratory in § 414.502 by referring to the CLIA definition at § 493.2 to indicate what we mean by laboratory.

We indicated in the proposed rule that, under the revised payment system for CDLTs, an applicable laboratory is the entity that reports applicable information to CMS. However, not all entities that meet the CLIA regulatory definition of laboratory would be applicable laboratories under our proposal. Here, we discuss which entities we believe should be required to report applicable information.

Laboratory business models vary throughout the industry. For example, some laboratories are large national networks with multiple laboratories under one parent entity. Some laboratories are single, independent laboratories that operate individually. Some entities, such as hospitals or large practices, include laboratories as well as other types of providers and suppliers. We proposed that an applicable laboratory is an entity that itself is a laboratory under the CLIA definition or is an entity that includes a laboratory (for example, a health care system that is comprised of one or more hospitals, physician offices, and reference laboratories). Within our proposed definition of applicable laboratory, we indicated that if the entity is not itself a laboratory, it has at least one component that is a laboratory, as defined in § 493.2.

We proposed that, whether an applicable laboratory is itself a laboratory or is an entity that has at least one component that is a laboratory, the applicable laboratory would be required to report applicable information. Entities that enroll in Medicare must provide a TIN, which we use to identify the entity of record that is authorized to receive Medicare payments. The TIN-level entity is the entity that reports tax-related information to the Internal Revenue Service (IRS). When an entity reports to the IRS, the entity and its components are all associated with that entity's TIN. We would rely on the TIN as the mechanism for defining the entity we consider to be the applicable laboratory. Therefore, we proposed that the TIN-level entity is the applicable laboratory.

We explained that each component of the TIN-level entity that is a covered health care provider under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations will have an NPI. The NPI is the HIPAA standard unique health identifier for health care providers adopted by HHS (§ 162.406). Health care providers, which include laboratories that transmit any health information in electronic form in connection with a HIPAA transaction for which the Secretary has adopted a standard, are required to obtain NPIs and use them according to the NPI regulations at 45 CFR part 162, subpart D. When the TIN-level entity reports tax-related information to the IRS, it does so for itself and on behalf of its component NPI-level entities. We indicated this in the proposed definition of applicable laboratory by stating that the applicable laboratory is the entity that reports tax-related information to the IRS under a TIN with which all of the NPIs in the entity are associated. We also proposed to define TIN and NPI in § 414.502 by referring to definitions already in the Code of Federal Regulations.

We considered defining an applicable laboratory at the NPI level instead of the TIN level. Some stakeholders indicated that, because they bill Medicare by NPI and not TIN, the NPI would be the most appropriate level for reporting applicable information to Medicare. However, because the purpose of the revised Medicare payment system is to base CLFS payment amounts on private payor rates for CDLTs, which we expect would be negotiated at the level of the entity's TIN, as described previously, and not by individual laboratory locations at the NPI level, we proposed that an applicable laboratory be defined at the level of a TIN. Further, numerous stakeholders suggested that the TIN represents the entity negotiating pricing and is the entity in the best position to compile and report applicable information across its multiple NPIs when there are multiple NPIs associated with a TIN. We stated in the proposed rule that we believed defining an applicable laboratory by TIN rather than by NPI would result in the same applicable information being reported, and would require reporting by fewer entities, and therefore, would be less burdensome to applicable laboratories. In addition, we stated that we did not believe reporting at the TIN level would affect or diminish the quality of the applicable information reported. To the extent the information is accurately reported, reporting at a higher organizational level should produce exactly the same applicable information as reporting at a lower level. Therefore, we proposed to define applicable laboratory by TIN rather than by NPI.

We also considered whether to separate the mechanics of reporting from the definition of an applicable laboratory. For example, we considered allowing or requiring a corporate entity with multiple TINs to provide applicable information for all of its TINs along with a list of component TINs. Under this approach, the corporate entity would report each distinct private payor rate and the associated volume across all component TINs instead of each component TIN reporting separately. Thus, if the same rate was paid by a private payor in two or more of the corporate entity's component TINs, the entity would report the private payor rate once and the associated sum of the volume of that test across the component TINs. We stated in the proposed rule that we believed this approach may be operationally less burdensome than submitting separate data files by TIN or NPI. We also stated that we did not believe such reporting would affect the quality of the applicable information because we should still arrive at the same weighted median for each test. We opted not to propose this option, however, because we are not familiar enough with the corporate governance of laboratories to know whether this even higher level of reporting would be a desirable or practical option for the industry and whether it would affect the quality of the applicable information we would receive.

Next, we considered what it means for an applicable laboratory to receive a majority of Medicare revenues from sections 1834A, 1833(h), or 1848 of the Act. We proposed to define Medicare revenues to be payments received from the Medicare program, which would include fee-for-service payments under Medicare Parts A and B, as well as Medicare Advantage payments under Medicare Part C, and prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance amounts for Medicare services furnished during the data collection period. We applied the standard meaning of "majority," which is more than 50 percent. Under our proposal, in deciding whether an entity meets the majority criterion of the applicable laboratory definition, it would examine its Medicare revenues from sections 1834A, 1833(h), and 1848 of the Act to determine if those revenues (including any beneficiary deductible and coinsurance amounts), whether from only one or a combination of all three sources, constitute more than 50 percent of its total revenues under the Medicare program for the data collection period. In determining its Medicare revenues from sections 1834A, 1833(h), and 1848 of the Act, the entity would not include Medicare payments made to hospital laboratories for tests furnished for admitted hospital inpatients or registered hospital outpatients because payments for these patient care services are made under the statutory authorities of section 1886(d) of the Act (for the Hospital Inpatient Prospective Payment System (IPPS)) and section 1833(t) of the Act (for the OPPS), respectively, not sections 1834A, 1833(h), or 1848 of the Act. In other words, an entity would need to determine whether its Medicare revenues from laboratory services billed on Form CMS 1500 (or its electronic equivalent) and paid under the current CLFS (section 1833(h) of the Act), the CLFS under PAMA (section 1834A of the Act), and the PFS (section 1848 of the Act) constitute more than 50 percent of its total Medicare revenues for the data collection period.

Moreover, for the entity evaluating whether it is an applicable laboratory, the "majority of Medicare revenues" determination would be based on the collective amount of its Medicare revenues received during the data collection period, whether the entity is a laboratory under § 493.2 or is a larger entity that has at least one component that is a laboratory. We proposed that the determination of whether an entity is an applicable laboratory would be made across the entire entity, including all component NPI entities, and not just those NPI entities that are laboratories. We proposed to specify in the definition of applicable laboratory that an applicable laboratory is an entity that receives, collectively with its associated NPI entities, more than 50 percent of its Medicare revenues from one or a combination of the following sources: 42 CFR part 414, subpart G; and 42 CFR part 414, subpart B. The regulatory citations we proposed to include in the definition are the regulatory payment provisions that correspond to the three statutory provisions named in section 1834A(a)(2), that is, sections 1834A, 1833(h), and 1848 of the Act.

We noted that section 1834A(a)(1) of the Act only mandates reporting from entities meeting the definition of an applicable laboratory. We stated in the proposed rule that we believed the purpose of only mandating applicable laboratories to report applicable information is to ensure we use only their applicable information to determine payment rates under the CLFS beginning January 1, 2017, and not information from entities that do not meet the definition of applicable laboratory. We believed that, by specifying that only applicable laboratories must report applicable information, and specifying in the definition of applicable laboratory that an applicable laboratory must receive the majority of its Medicare revenues from PFS or CLFS services, the statute limits reporting primarily to independent laboratories and physician offices (other than those that meet the low expenditure or low volume threshold, if established by the Secretary) and does not include other entities (such as hospitals or other health care providers) that do not receive the majority of their revenues from PFS or CLFS services. For this reason, we proposed to prohibit any entity that does not meet the definition of applicable laboratory from reporting applicable information to CMS, which we reflect in paragraph (g) of the proposed data reporting requirements in § 414.504.

We stated that we expected most entities that fall above or below the "majority of Medicare revenues" threshold will tend to maintain that status through the course of their business. However, it is conceivable that an entity could move from above to below the threshold, or vice-versa, through the course of its business so that, for example, for services furnished in one data collection period, an entity might be over the "majority of Medicare revenues" threshold, but below the threshold in the next data collection period. We proposed that an entity that otherwise meets the criteria for being an applicable laboratory, would have to report applicable information if it is above the threshold in the given data collection period. Some entities will not know whether they exceed the threshold until after the data collection period is over; in that case, they would have to retroactively assess their Medicare revenues during the 3-month data reporting period. However, we expected that most entities will know whether they exceed the threshold long before the end of the data collection period. Under our proposal, an entity would need to reevaluate its status as to whether it falls above or below the "majority of Medicare revenues" threshold for every data collection period, that is, every year for ADLTs and every 3 years for all other CDLTs. We proposed this requirement would be reflected in the definition of applicable laboratory in § 414.502.

Finally, we proposed to establish a low expenditure threshold for excluding an entity from the definition of applicable laboratory, as permitted under section 1834A(a)(2) of the Act, and we included that threshold in our proposed definition of applicable laboratory in § 414.502. We stated in the proposed rule that we believed it is important to achieve a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a test, and minimizing the reporting burden for entities that receive a relatively small amount of revenues under the CLFS. We expected many of the entities that meet the low expenditure threshold will be physician offices and will have relatively low revenues for laboratory tests paid under the CLFS.

For purposes of determining the low expenditure threshold, we reviewed Medicare payment amounts for physician office laboratories and independent laboratories from CY 2013 Medicare CLFS claims data. In the proposed rule, we noted that, although the statute uses the term "expenditure," in this discussion, we would use the term "revenues" because, from the perspective of applicable laboratories, payments received from Medicare are revenues rather than expenditures, whereas expenditures refer to those same revenues, but from the perspective of Medicare (that is, to Medicare, those payments are expenditures). In our analysis, we assessed the number of billing physician office laboratories and independent laboratories that would otherwise qualify as applicable laboratories, but would be excluded from the definition under various revenue thresholds. We did not include in our analysis hospitals whose Medicare revenues are generally under section 1833(t) of the Act for outpatient services and section 1886(d) of the Act for inpatient services, as these entities are unlikely to meet the proposed definition of applicable laboratory.

We found that, with a $50,000 revenue threshold, the exclusion of data from physician office laboratories and independent laboratories with total CLFS revenues below that threshold, did not materially affect the quality and sufficiency of the data we needed to set rates. In other words, we were able to substantially reduce the number of entities that would be required to report (94 percent of physician office laboratories and 52 percent of independent laboratories) while retaining a high percentage of Medicare utilization (96 percent of CLFS spending on physician office laboratories and more than 99 percent of CLFS spending on independent laboratories) from applicable laboratories that would be required to report. In the proposed rule, we indicated that we did not believe excluding certain entities with CLFS revenues below a $50,000 threshold would have a significant impact on the weighted median private payor rates.

With this threshold, using Medicare utilization data, we estimated that only 17 tests would have utilization completely attributed to laboratories not reporting because they fell below a $50,000 threshold. We understand that Medicare claims data are not representative of the volume of laboratory tests furnished in the industry as a whole; however, we believed this was the best information available to us for the purpose of determining a low expenditure threshold for the proposed rule. Therefore, we proposed that any entity that would otherwise be an applicable laboratory, but that receives less than $50,000 in Medicare revenues under section 1834A and section 1833(h) of the Act for laboratory tests furnished during a data collection period, would not be an applicable laboratory for the subsequent data reporting period. In determining whether its Medicare revenues from sections 1834A and 1833(h) are at least $50,000, the entity would not include Medicare payments made to hospital laboratories for tests furnished for hospital inpatients or hospital outpatients. In other words, an entity would need to determine whether its Medicare revenues from laboratory tests billed on Form CMS 1500 (or its electronic equivalent) and paid under the current CLFS (under section 1833(h) of the Act) and the revised CLFS (under section 1834A of the Act) are at least $50,000. We proposed that if an applicable laboratory receives, collectively with its associated NPI entities (which would include all types of NPI entities, not just laboratories), less than $50,000 in Medicare revenues for CLFS services paid on Form CMS 1500 (or its electronic equivalent), the entity would not be an applicable laboratory.

As discussed in the proposed rule (80 FR 59399), we proposed an initial data collection period of July 1, 2015, through December 31, 2015 (all subsequent data collection periods would be a full calendar year). In conjunction with the shortened data collection period for 2015, we proposed to specify that, during the data collection period of July 1, 2015, through December 31, 2015, to be an applicable laboratory, an entity must have received at least $25,000 of its Medicare revenues from the CLFS, as set forth in 42 CFR part 414, subpart G. During each subsequent data collection period, to be an applicable laboratory, an entity would have to receive at least $50,000 of its Medicare revenues from the CLFS, as set forth in 42 CFR part 414, subpart G.

We stated that, as with the "majority of Medicare revenues" threshold, some entities will not know whether they meet the low expenditure threshold, that is, if they receive at least $50,000 in Medicare CLFS revenues in a data collection period (or $25,000 during the initial data collection period) until after the data collection period is over; in that case, they would have to retroactively assess their total Medicare CLFS revenues during the subsequent 3-month data reporting period. However, for many entities, it will be clear whether they exceed the low expenditure threshold even before the end of the data collection period. Under our proposal, an entity would need to reevaluate its status as to the $50,000 low expenditure threshold during each data collection period, that is, every year for ADLTs and every three years for all other CDLTs. We proposed to codify the low expenditure threshold requirement as part of the definition of applicable laboratory in § 414.502.

We did not propose a low volume threshold. As indicated in the proposed rule, once we obtain applicable information under the new payment system, we may decide to reevaluate the threshold options in future years and propose different or revised policies, as necessary, which we would do through notice and comment rulemaking.

In summary, we proposed to define an applicable laboratory to mean an entity that reports tax-related information to the IRS under a TIN with which all of the NPIs in the entity are associated. An applicable laboratory would either itself be a laboratory, as defined in § 493.2, or, if it is not itself a laboratory, have at least one component that is. In a data collection period, an applicable laboratory must have received, collectively with its associated NPI entities, more than 50 percent of its Medicare revenues from either the CLFS or PFS. For the data collection period from July 1, 2015 through December 31, 2015, for purposes of calculating CY 2017 payment rates, the applicable laboratory must have received, collectively with its associated NPI entities, at least $25,000 of its Medicare revenues from the CLFS, and for all subsequent data collection periods, at least $50,000 of its Medicare revenues from the CLFS. We proposed to codify this definition of applicable laboratory in § 414.502.

A discussion of the comments we received on our proposed definition of applicable laboratory and our responses to those comments are provided below.

Comment: While some commenters agreed with our proposal to designate applicable laboratories according to an entity's TIN, many objected. Those that objected asserted overwhelmingly that defining an applicable laboratory using the TIN would exclude hospital laboratories from the definition of applicable laboratory because, in calculating the applicable laboratory's majority of Medicare revenues amount, which looks at the percentage of Medicare revenues from the PFS and CLFS across the entire TIN-level entity, virtually all hospital laboratories would not be considered an applicable laboratory. Commenters stated that hospital laboratories compete with independent laboratories and therefore must be able to report private payor rates in order for CMS to more accurately reflect the private payor market for laboratory services under the revised CLFS.

Many commenters expressed particular concern about the exclusion of hospital outreach laboratories under our proposed definition of applicable laboratory. Commenters asserted that hospital outreach laboratories, which do not provide laboratory services to hospital patients, are direct competitors of the broader independent laboratory market, and excluding them from the definition of applicable laboratory would result in incomplete and inappropriate applicable information, which would skew the CLFS payment rates. Commenters maintained that, if the majority of all laboratories are not permitted to report private payor rate information, CMS's policy would ignore the intent of Congress to include all sectors of the laboratory market in establishing the new Medicare rates for clinical diagnostic laboratory services. Commenters stressed that, in order to set accurate market-based rates, CMS needs to ensure reporting by a broad scope of the laboratory market.

Response: We believe the statute supports the effective exclusion of hospital laboratories by virtue of the majority of Medicare revenues criterion in section 1834A(a)(2) of the Act. Section 1834A(a)(2) provides that, to qualify as an applicable laboratory, the majority of the laboratory's Medicare revenues are derived from the CLFS or the PFS (the laboratory's total Medicare revenues being the denominator, and revenues from the CLFS and PFS being the numerator in the ratio). Under our proposal, an entity would determine its total Medicare payments received from the Medicare program, including fee-for-service payments under Medicare Parts A and B, as well as Medicare Advantage payments under Medicare Part C, and prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance amounts for Medicare services furnished during the data collection period. An entity would then calculate its revenues from sections 1834A, 1833(h), and 1848 of the Act to determine if those revenues (including any beneficiary deductible and coinsurance amounts), whether from only one or a combination of all three sources, constituted more than 50 percent of its total revenues under the Medicare program for the data collection period. Because payments for IPPS and OPPS services are made under the statutory authorities of sections 1886(d) and 1833(t) of the Act, respectively, not sections 1834A, 1833(h), or 1848, they would not be included in the numerator of the ratio. Most hospital laboratories will not meet the majority of revenues threshold because their revenues under the IPPS and OPPS alone will likely far exceed the revenues they receive under the CLFS and PFS. Therefore, we believe the statute supports limiting reporting primarily to independent laboratories and physician offices.

We agree with commenters, however, that hospital outreach laboratories should be accounted for in the new CLFS payment rates. Hospital outreach laboratories are laboratories that furnish laboratory tests for patients that are not admitted hospital inpatients or registered outpatients of the hospital. They are distinguishable from hospital laboratories in that they are enrolled in Medicare separately from the hospital of which they are a part, that is, they can be enrolled as independent laboratories that do not serve hospital patients. We believe it is important not to prevent private payor rates from being reported for hospital outreach laboratories so that we may have a broader representation of the national laboratory market to use in setting CLFS payment amounts. We address below how we are revising our definition of applicable laboratory to account for hospital outreach laboratories.

Comment: Many commenters recommended that the CLIA certificate, rather than the TIN, be used to identify the organizational entity that would be considered an applicable laboratory. Under this approach, each entity that has a CLIA certificate would be an applicable laboratory. They explained that because the denominator of the majority of Medicare revenues ratio would only include PFS and CLFS revenues, the denominator would more or less equal the numerator of the formula and would therefore ensure that an entity exceeded the threshold criterion. Another commenter, that requested applicable laboratory be defined by the CLIA certificate, suggested the following approach for calculating the majority of Medicare revenues amount. If CMS used the CLIA certificate to define applicable laboratory, then a hospital laboratory's Medicare revenues from PFS and CLFS would be compared to the hospital laboratory's total Medicare revenues, including Medicare laboratory revenue obtained from inpatient and outpatient hospital laboratory sources, as opposed to the hospital's total Medicare revenue. Commenters believed this approach would qualify hospital laboratories as applicable laboratories, which would allow for the reporting of market-based payment rates, as they believe Congress intended.

Response: We considered the commenters' suggestions to define applicable laboratory by CLIA certificate. As we indicated above, we do not believe it is appropriate to establish an applicable laboratory definition to purposely qualify hospital laboratories as applicable laboratories. We do, however, distinguish hospital outreach laboratories from hospital laboratories (as discussed above), and believe we should define applicable laboratory so that hospital outreach laboratories would not, in effect, be excluded. In addition to the potential for a CLIA certificate-based definition of applicable laboratory to be overly inclusive by including all hospital laboratories, not just hospital outreach laboratories, we do not agree with commenters as to how the majority of Medicare revenues criterion would be applied with this option.

If we used the commenters' suggested approach to define an applicable laboratory by CLIA certificate, the majority of Medicare revenues criterion would be applied only to the revenues received by the laboratory (as identified by its CLIA certificate) and not to the entire organization, if the laboratory is part of an organization that provides laboratory and other services. For example, in the case of a hospital laboratory, the numerator of the majority of Medicare revenues ratio would be the revenues the hospital received for the CLFS and PFS services furnished in its laboratory, and the denominator would be all of the revenues the hospital received for the laboratory services provided to hospital inpatients and outpatients. However, as laboratory services provided to hospital inpatients and outpatients are typically not separately paid, it is unclear to us how revenues for these services would be determined for the denominator of the ratio. Laboratory services provided to Medicare hospital inpatients are not paid on a fee-for-service basis, but rather, are bundled into Medicare's IPPS. In addition, beginning January 1, 2014, 3 months prior to the enactment of PAMA, CMS began packaging nearly all laboratory services performed for registered hospital outpatients into the OPPS. Thus, most hospital outpatient laboratory services are also not paid on a fee-for-service basis.

The CLIA certificate is used to certify that a laboratory meets applicable health and safety regulations in order to furnish laboratory services. CLIA certificates are not associated with Medicare billing so, unlike for example, the NPI, with which revenues for specific services can easily be identified, the CLIA certificate cannot be used to identify revenues for specific services. The TIN, like the NPI, can be used to determine revenues and costs for tax purposes where revenues for CLFS or PFS services can be distinguished from other Medicare revenues. We do not see how a hospital would determine whether its laboratories would meet the majority of Medicare revenues threshold (and the low expenditure threshold) using the CLIA certificate as the basis for defining an applicable laboratory. In addition, given the difficulties many hospitals would have in determining whether their laboratories are applicable laboratories, we also believe hospitals may object to using the CLIA certificate as commenters advocate.

Comment: One commenter, concerned that our proposed definition of applicable laboratory would exclude hospital outreach services, suggested an alternative approach so that hospital outreach laboratories could potentially be included. Under the commenter's approach, the hospital would determine the proportion of its overall Medicare revenues attributable to the hospital laboratory and whether the hospital laboratory derives a majority of its Medicare revenues from the CLFS and PFS. The commenter suggested, in order to determine the total Medicare revenues attributed to the hospital laboratory, a hospital could establish an adjustment factor based on its payment-to-charges ratio. The adjustment factor would be applied to the hospital's total Medicare revenues received at the TIN level to determine the portion of Medicare revenues attributed to the hospital laboratory. The hospital would then add the revenues paid under the CLFS and PFS for non-hospital patients and for non-bundled outpatient laboratory services, the sum of which would be the estimated total Medicare revenues attributed to the hospital laboratory (the denominator). Under the commenter's approach, the majority of Medicare revenues threshold would be applied to the hospital's laboratory rather than to the entire hospital. If the hospital laboratory revenues from the PFS and CLFS exceeded 50 percent of the hospital laboratory's total Medicare revenue, it would meet the majority of Medicare revenues threshold.

Response: As discussed below, we are defining applicable laboratory at the NPI level, which we believe addresses the industry's concern that hospital outreach laboratories not be excluded from the definition of applicable laboratory. Given this change in how we are defining applicable laboratory, we do not believe it is necessary to establish a hospital adjustment factor to enable hospital outreach laboratories to be applicable laboratories. Hospital outreach laboratories will be able to be included as applicable laboratories under the final policy we are adopting.

Comment: Many commenters recommended that the definition of applicable laboratory be established at the NPI level rather than the TIN level because doing so would increase the number of hospital laboratories that would qualify as applicable laboratories. They stated that the NPI is included on claims submitted by laboratories and can be easily used to determine whether the laboratory meets the majority of Medicare revenues criterion for being an applicable laboratory. Other commenters were opposed to defining applicable laboratory in terms of the NPI because they believed not all laboratories are identified separately by an NPI. They stated that very few hospital laboratories have laboratory-specific NPIs, even those with robust laboratory outreach programs, and laboratory services claims are generally submitted under the hospital's NPI. However, commenters that favored using the NPI suggested hospital laboratories that function as outreach laboratories may enroll in Medicare as independent laboratories, under a separate NPI, in which case they could meet the definition of applicable laboratory. They believed this approach would ensure that hospital outreach laboratories, in particular, would meet the definition of applicable laboratory.

Response: We considered the commenters' suggestions to define applicable laboratory by the NPI rather than the TIN. Under this approach, the criteria for being an applicable laboratory would be applied by each laboratory with an NPI. So, for example, in determining whether the majority of Medicare revenues criterion is met, the NPI-level entity would compare its revenues under the CLFS and PFS to its own total Medicare revenues which, in the case of a hospital outreach laboratory, could presumably be comprised of only CLFS and PFS revenues. A primary benefit to this approach is that it would allow a hospital outreach laboratory, either currently enrolled in Medicare as an independent laboratory (in which case it would already have its own NPI) or that obtains a unique NPI (separate from the hospital) and bills for its hospital outreach services (that is, services furnished to patients other than inpatients or outpatients of the hospital) using its unique NPI, to meet the definition of an applicable laboratory. As we discussed above, an advantage of enabling private payor rates to be reported for hospital outreach laboratories is that there will be a broader representation of the national laboratory market on which to base CLFS payment amounts. Hospital laboratories that are not outreach laboratories, on the other hand, would be unlikely to get their own NPI and bill Medicare for laboratory services because the laboratory services they furnish are typically primarily paid for as part of bundled payments made to the hospital under the IPPS and OPPS.

As discussed previously in this section, given that the purpose of the revised Medicare payment system is to base CLFS payment amounts on private payor rates, which we expect would be negotiated at the level of the entity's TIN and not by individual laboratory locations at the NPI level, we proposed that an applicable laboratory be defined at the TIN level instead of the NPI level. In addition, while we were developing the proposed rule, many stakeholders suggested that the TIN-level entity is the one that negotiates pricing and is in the best position to collect private payor rates and report applicable information for its multiple NPI-level entities when there are multiple NPI-level entities associated with a TIN. Defining applicable laboratory in terms of the NPI rather than the TIN, however, is consistent with our view that the statute supports limiting reporting to primarily independent laboratories and physician office laboratories. That is, the statute defines an applicable laboratory as a laboratory that receives a majority of its

Medicare revenues from the PFS and the CLFS, which predominantly includes independent laboratories and physician office laboratories.

However, we proposed to define applicable laboratory in terms of the TIN rather than the NPI, in part, to minimize the reporting burden on the laboratory industry. We have concerns about the administrative burden the reporting requirement may place on applicable laboratories by defining applicable laboratories in terms of the NPI. We believe that defining applicable laboratory by the NPI, while retaining the reporting requirement at the TIN level, will result in the same applicable information being reported to CMS, but will require reporting by fewer entities, which will be less burdensome to the laboratory industry. Therefore, although we are changing the definition of applicable laboratory to apply at the NPI level, we are retaining the requirement to report applicable information at the TIN level. Under this approach, the TIN-level entity will still be required to report applicable information to CMS for all of its component NPI-level entities that meet the definition of applicable laboratory. We are calling these TIN-level entities "reporting entities" and are establishing a definition in § 414.502, which we discuss in more detail in this section.

We are not prescribing how a reporting entity should coordinate with its component applicable laboratories to collect and prepare applicable information for submission. The TIN-level entity and any NPI-level entities that are applicable laboratories will establish their own approach for ensuring that the TIN-level entity reports applicable information for laboratory services provided by the NPI-level entities. However, in deciding how to collect applicable information and prepare it for reporting, entities may want to consider that, in this final rule, data integrity will be certified for the reporting entity under § 414.504(d) (as discussed in section II.E.2), and the reporting entity will be the entity to which civil penalties may be applied under § 414.504(e) (as discussed in section II.E.1). We will provide the details for how applicable information is to be reported to CMS through subregulatory guidance.

In light of the changes described above, we are modifying our proposed definition of applicable laboratory at § 414.502. Specifically, we are removing the first two requirements from the proposed definition that pertained to the TIN-level entity. Because all NPI-level entities that qualify as applicable laboratories will be laboratories, we are specifying that an applicable laboratory is a laboratory as defined in § 493.2 that bills Medicare part B under its own NPI. Because we are defining applicable laboratory in terms of the NPI rather than the TIN, we are specifying in the definition of applicable laboratory that the majority of Medicare revenues threshold is to be applied by the NPI-level entity, that is, the applicable laboratory, rather than by the TIN-level entity collectively with all its associated NPIs.

In addition, as discussed later in this section, we are revising the dollar amount for the low expenditure threshold from $50,000 to $12,500, which is also reflected in the revised definition of applicable laboratory. And, because the initial data collection period will no longer be shorter than the subsequent data collection periods (as discussed further below), the definition of applicable laboratory will no longer reflect a different low expenditure threshold for the initial data collection period. Additionally, as discussed later in this section, we are also not applying the low expenditure threshold to the single laboratory that offers and furnishes an ADLT with respect to that laboratory's ADLTs, so we are adding a provision to that effect.

Comment: Many commenters suggested that CMS should separate the reporting of applicable information from the definition of applicable laboratory. Commenters recommended that, even if applicable laboratories are defined at the NPI level, the data reporting requirement should remain with the TIN-level entity. Some commenters who recommended that we identify applicable laboratories by CLIA certificate also suggested a bifurcated approach to defining applicable laboratory and reporting applicable information whereby applicable laboratories would be identified by CLIA certificates, and the businesses that own the CLIA certificate-level entities would report applicable information in one report by either their TIN or NPI.

While many commenters supported our proposal for reporting applicable information at the TIN level, some commenters also suggested that we be flexible in allowing applicable information to be reported at the TIN level, the NPI level, or the CLIA certificate level.

Response: We considered commenters' suggestions to continue to require the TIN-level entity to report applicable information even if we decided to define the applicable laboratory at a level other than the TIN. As discussed above, we are defining applicable laboratory at the NPI level, so under the approach suggested by commenters, while the NPI-level entity would be the applicable laboratory, the TIN-level entity would report the NPI-level entity's applicable information. Depending on the entity's organizational structure, sometimes the NPI-level entity will be a component of the TIN-level entity, but sometimes it will itself also be the TIN-level entity, for example, when a laboratory, as defined in § 493.2, is not owned by and does not own other entities. Therefore, sometimes the applicable laboratory will also be the reporting entity.

We believe that reporting at the TIN level will require reporting from fewer entities overall and will therefore be less burdensome to all types of applicable laboratories—that is independent laboratories, physician office laboratories, and hospital outreach laboratories—than would requiring applicable laboratories to report. We indicated in the proposed rule (80 FR 59392) that we do not believe reporting at the TIN level would affect or diminish the quality of the applicable information reported, and we noted that reporting at the higher level should produce exactly the same applicable information as reporting at the lower level. We still believe that to be the case even though we are no longer defining applicable laboratory to be the TIN-level entity.

We do not agree with the comments suggesting we allow applicable information to be reported at the TIN level, the NPI level, or the CLIA certificate level. We believe such flexibility could result in confusion among applicable laboratories as to which entity will be reporting for a given data reporting period. For example, under the commenters' suggested approach, for an organization in which a TIN-level entity is comprised of multiple NPI-level entities that meet the definition of applicable laboratory, the organization might designate an NPI-level entity to report applicable information for the initial data reporting period, but might decide to shift the reporting responsibility to the another NPI-level entity or the TIN-level entity for the next. We are concerned about the possibility of confusion as to which entity has reporting responsibilities, which could result in duplicative or no reporting.

For these reasons, we are finalizing our proposal that applicable information must be reported by the TIN-level entity. We believe section 1834A(a)(1) of the Act supports this final policy. A fundamental requirement of the statute is that the applicable information of applicable laboratories must be reported. While we are operationalizing section 1834A(a)(1) of the Act by designating an entity other than the applicable laboratory to report, we are adhering to the essential requirement of the statute. Accordingly, we are adding the definition of reporting entity to § 414.502 to state that the reporting entity is the entity that reports tax-related information to the Internal Revenue Service using its TIN for its components that are applicable laboratories. We are also revising the data reporting requirements in § 414.504(a) to require a reporting entity to report applicable information for each CDLT furnished by its component applicable laboratories.

Comment: Many commenters requested that laboratories not meeting the definition of applicable laboratory still be permitted to voluntarily report private payor rates. The commenters urged us to consider allowing an option whereby laboratories that do not meet the definition of applicable laboratory may still report applicable information if they wish to do so. They contend that this option would make the new rates under the revised CLFS, which are based on the median of private payor rates, more representative of the total laboratory market. One commenter stated that our proposal to prohibit any entity that does not meet the definition of applicable laboratory from reporting applicable information does not appear in the statute and is not inferable from the statute. Another commenter suggested that an entity, that is not itself an applicable laboratory but that has the ability to report applicable information more efficiently and effectively than the applicable laboratories it owns or controls, should be permitted to do so.

Response: The statute is clear about the particular information that is to be reported and on which we must base the new CLFS payment rates. Only applicable information of applicable laboratories is to be reported, and section 1834A(a)(3) of the Act indicates that applicable information is private payor rate information. The statute imposes parameters on the collection and reporting of private payor rate information, and section 1834A(b) of the Act specifies that the payment amounts for CDLTs are to be based on the median of the private payor rate information. As such, we believe the statute supports our policy to prohibit information other than statutorily specified private payor rate information of applicable laboratories from being reported and used to set CLFS payment amounts under the revised CLFS. Therefore, we do not agree with the commenters' recommendation to allow voluntary reporting. At § 414.504(g), we proposed that an entity that does not meet the definition of an applicable laboratory may not report applicable information. We are finalizing that requirement, but rephrasing it as follows to conform to our final policy that reporting entities are distinct from applicable laboratories: Applicable information may not be reported for an entity that does not meet the definition of an applicable laboratory.

Comment: Two commenters stated that our proposed low expenditure threshold would have a negative effect on the pricing of point of care tests provided by physician office laboratories (POLs). Point of care tests will be priced by crosswalking or gapfilling methodologies if they are only furnished by POLs that are below the low expenditure threshold, or they will be priced using only private payor rate information furnished by independent laboratories (which only provide a minority of these tests), and those rates could be lower than the rates paid by private payors to POLs.

The commenters suggested we establish a POL-dependent test CLFS revenue threshold to address POLs performing tests that are performed primarily or exclusively in the POL setting. Specifically, they proposed that CMS identify test codes for which POLs perform the test 50 percent or more of the time (by procedure volume). The commenters suggested that CMS could identify any POL that would not otherwise meet the definition of applicable laboratory (because the laboratory is below the low expenditure threshold) but that performs more than a significant threshold percentage, as determined by CMS, of the POL-dependent test. The commenters stated that CMS would contact such POLs and require that they report applicable information solely for those POL-dependent tests, so POL laboratories would not report applicable information for any test codes other than for POL-dependent tests that meet the criteria suggested. Furthermore, the POL could decline to report if it did not perform the test during the data collection period. Additionally, the commenter suggested for the purpose of reporting POL-dependent tests, a data collection period should be limited to no more than 3 months (or some other appropriate timeframe that balances the benefit of enhanced data collection with avoiding unnecessary reporting burden on physician offices). Moreover, the commenter requested that POL test-dependent laboratories not be liable for the civil monetary penalties outlined in the statute for good-faith errors in reporting. Under the suggested approach, for each POL-dependent test code, CMS would combine the data reported by applicable laboratories together with the data from POLs meeting the POL-dependent test CLFS revenue threshold for that test to determine the weighted median private payor amount.

Response: We considered establishing a POL-dependent test CLFS revenue threshold based on criteria we set that could potentially achieve the goal of increasing reporting for POL tests. Under this approach, we could identify the POL-dependent test codes that a POL must report and establish a low volume or low expenditure threshold above which a POL would be required to report private payor data. Although we acknowledge that, without a POL-dependent test CLFS revenue threshold, our payment methodology could result in the use of crosswalking or gapfilling instead of private payor data to establish rates for tests furnished exclusively in the POL setting, our data show that the number of laboratory tests that are exclusively or primarily performed by POLs is not significant. Furthermore, as discussed in the proposed rule (80 FR 59394), we estimated there are only 17 tests on the CLFS for which we would receive no data under our proposed definition of applicable laboratory with the low expenditure threshold. Therefore, we have decided not to pursue the commenters' suggested approach. In addition, we note that the statute does not support exempting some laboratories from the application of CMPs, as commenters suggest. We also note that we cannot provide information on the effect on revenue for POLs without knowing the resulting crosswalked or gapfilled amount determined for these tests and what would have been paid using the weighted median private payor rate. Although we have decided not to establish a POL-dependent test CLFS revenue threshold in this final rule, we may revisit the issue in a future rule as we gain more programmatic experience under the new CLFS and continue to refine payment for laboratory tests under the CLFS.

Comment: One commenter disagreed with our analysis of the amount of data we expect to receive under the proposed low expenditure threshold. The commenter stated that it appears the low expenditure threshold would result in all laboratories above the low expenditure threshold being required to report, despite some payment rate information, such as payments made on a capitated or other similar payment basis, being statutorily excluded from the definition of applicable information. The commenter contended that, without knowledge of contractual arrangements between laboratories and private payors, CMS's estimation of the amount of applicable information it will be collecting, even after applying the low expenditure threshold, is undoubtedly overstated. The commenter stated that the quality and sufficiency of data needed to set rates is unknown and therefore requested a significant decrease in the low expenditure threshold in order to ensure the volume of private payor rate data collected is sufficient.

Response: We are not decreasing the low expenditure threshold in response to this comment; however, we are decreasing it commensurate with the shorter data collection period we are finalizing in this rule, as discussed below. We do not agree with the commenter's reasons for significantly decreasing the low expenditure threshold. First, a significant decrease in the low expenditure threshold could potentially result in a significant increase in the reporting burden on the laboratory industry without a proportionate improvement in the quality and accuracy of the data reported. Second, we continue to believe our analysis, which suggests we will receive a very high percentage of market data with the low expenditure threshold we proposed, is reliable. While we acknowledge that our analysis based on Medicare CLFS data is not a perfect proxy for private payor rate data, it reflects the type of private payor rates that will be reported as applicable information by applicable laboratories. For instance, by excluding capitated payments and other similar payments, the statute predominately defines applicable information as fee-for-service (FFS) private payor rates. Therefore, as discussed later in this section, to determine the low expenditure threshold, we reviewed Medicare FFS payment amounts from CY 2013 Medicare CLFS claims data. Based on our analysis, we found that setting a $12,500 threshold and using data collected at the NPI level for a 6-month data collection period, we could retain a high percentage of Medicare FFS utilization under the CLFS from the applicable information reported for applicable laboratories. Further, because CLFS payments will be based on the weighted median of private payor rates, additional reporting may not be likely to change payment amounts, irrespective of how many additional smaller laboratories are required to report, if, as our analysis suggests, the largest laboratories dominate the market and therefore most significantly affect the payment rates. Once we obtain applicable information under the new payment system, we may decide to reevaluate the low expenditure threshold in future years and propose a different threshold amount through notice and comment rulemaking.

Comment: One commenter requested that we not apply the low expenditure threshold to laboratories that offer and furnish new ADLTs. The commenter stated that, by definition, a new ADLT is furnished by a single laboratory. Thus, if the laboratory that furnishes the new ADLT has under $50,000 in Medicare CLFS revenues, there will be no private payor data for the laboratory to report, even though the statute specifically includes provisions for reporting private payor data by the end of the second quarter of the new ADLT initial period and on annual basis thereafter. If no private payor data is reported, payment amounts will be determined under gapfilling or crosswalking methodologies which, the commenter contends, negates the intention of the statute, which is for new ADLTs to be priced based on reported private payor rates. Therefore, the commenter believes the low expenditure threshold should not apply to those applicable laboratories that offer and furnish new ADLTs. However, the commenter requested that, if CMS does apply a low expenditure threshold to laboratories that offer and furnish new ADLTs, it should do so consistent with the proposed low expenditure threshold for the initial data collection period, that is, $25,000 in Medicare revenues under the CLFS, in order to correspond to the shorter data collection period for ADLTs during the new ADLT initial period.

Response: The statute requires the applicable information of applicable laboratories to be reported and defines an applicable laboratory as one that derives the majority of its Medicare revenues from the PFS and CLFS. The statute also provides the Secretary with the authority to establish a low volume or low expenditure threshold as the Secretary determines appropriate. As such, the application of the majority of Medicare revenues threshold criterion is mandatory for defining an applicable laboratory, while the application of the low expenditure threshold criterion is discretionary for defining an applicable laboratory.

As noted by the commenter, we would not receive private payor rate data from laboratories offering and furnishing an ADLT that have CLFS revenues below the low expenditure threshold, which means we would need to use crosswalking or gapfilling methodologies to develop a payment amount for the test after the new ADLT initial period. Given that the statute contemplates private payor rates being reported for ADLTs by the end of the second quarter of the new ADLT initial period, we do not believe it is appropriate to apply a discretionary threshold if it excludes the single laboratory that offers and furnishes an ADLT from the definition of an applicable laboratory. If the single laboratory offering and furnishing an ADLT is excluded, we would not receive any private payor rate data for the test. For this reason, we agree with the commenter that the low expenditure threshold should not be applied to single laboratories offering and furnishing ADLTs. Therefore, we are finalizing a policy to exclude laboratories offering and furnishing ADLTs from the low-expenditure threshold, but only with respect to the ADLTs offered and furnished by the single laboratory. If the single laboratory offering and furnishing an ADLT otherwise meets the definition of applicable laboratory, but does not meet the low expenditure threshold, that is, even if it receives less than $12,500 in Medicare revenues from the CLFS during a data collection period, the single laboratory would be an applicable laboratory with respect to its ADLT, which means its applicable information for the ADLT must be reported. However, because we want to minimize the data collection and reporting burden for laboratories to the extent we can, with respect to the other CDLTs the single laboratory furnishes that are not ADLTs, the low expenditure threshold will still apply. This means that the single laboratory offering and furnishing an ADLT that does not receive at least $12,500 in Medicare CLFS revenues is not an applicable laboratory with respect to its CDLTs that are not ADLTs, and it may not report information for those other CDLTs. For example, if the single laboratory that offers and furnishes an ADLT receives greater than 50 percent of its Medicare revenue from the CLFS and PFS during a data collection period but only receives $10,000 in revenues from the CLFS during the data collection period, it would be an applicable laboratory only for the purpose of reporting applicable information for the ADLT. The single laboratory that offers and furnishes an ADLT would not be an applicable laboratory for purposes of the other CDLTs it furnishes that are not ADLTs.

In this circumstance, the single laboratory would report applicable information for the ADLT during the data reporting period, but would not report applicable information for the other CDLTs it furnishes that are not an ADLT. However, if the single laboratory meets the majority of Medicare revenue threshold, that is, it receives greater than 50 percent of its Medicare revenues from the CLFS and PFS during a data collection period and also meets the low expenditure threshold, that is, it receives at least $12,500 in revenues from the CLFS during the data collection period, it would be an applicable laboratory for purposes of all of its CDLTs, that is, ADLTs and other CDLTs that are not an ADLT, and it would report applicable information for all of its tests during the data reporting period. We are revising our definition of applicable laboratory in § 414.502 accordingly. We are also adding the following statement to § 414.504(g) to account for our policy that may result in a single laboratory being an applicable laboratory with respect to its ADLTs but not with respect to its other CDLTs: For a single laboratory that offers and furnishes an ADLT that is not an applicable laboratory except with respect to its ADLTs, the applicable information of its CDLTs that are not ADLTs may not be reported.

Comment: Many commenters referenced a report by the Department of Health and Human Services Office of the Inspector General (OIG) entitled “Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data.” The commenters stated that the OIG report showed 19 percent of Medicare CLFS payments went to physician office laboratories, 24 percent went to hospital-based laboratories, and 57 percent went to independent laboratories. The commenters urged us to define applicable laboratory in a way that reflects the actual laboratory marketplace, consistent with the ratio identified by the OIG. One commenter stated that this ratio could be achieved by adjusting the low expenditure threshold up or down until the desired percentages are obtained.

Response: We do not agree with commenters that an applicable laboratory should be defined so as to achieve the ratio of physician office laboratories, independent laboratories, and hospital-based laboratories consistent with what the OIG report showed. We believe this approach would place an undue administrative burden on physician office laboratories. For instance, based on the findings from the OIG report, nearly 20 percent of all physician office laboratories would be applicable laboratories. Given that the new CLFS payment methodology is based on the weighted median private payor rate, it is unlikely that including additional small physician office laboratories would have a material impact on payment amounts; the analysis we used to establish the low expenditure threshold suggests that the volume from larger laboratories would dominate the market and therefore the determination of the weighted median private payor rate.

Comment: A few commenters urged us to establish a low volume threshold that would exclude end-stage renal disease (ESRD) laboratories from the definition of applicable laboratory. The commenters stated that almost all ESRD-related laboratory testing is bundled into a per-patient payment that Medicare pays directly to the dialysis facility, and the ESRD laboratory is paid by the dialysis facility for the bundled laboratory services they furnish to Medicare beneficiaries. The commenters noted that the only Medicare CLFS revenues ESRD laboratories receive directly are for laboratory tests that are not related to renal disease. The commenters contend that this small number of non-ESRD-related laboratory tests furnished to Medicare beneficiaries would result in the ESRD specialty laboratories being considered applicable laboratories, although they have little private payor data to report. One commenter stated that ESRD laboratories with Medicare CLFS test volume of less than 5 percent of their total test volume for Medicare patients should be excluded from the definition of applicable laboratory. However, the same commenter also supported the majority of Medicare revenues threshold requiring at least 50 percent of total Medicare revenues be derived from the PFS and CLFS, which the commenter believes reflects the reality of accounting for Medicare revenues related to the ESRD PPS.

Response: We established the low expenditure threshold, in part, to alleviate the reporting burden on small laboratories that are likely to have a relatively low volume of CLFS claims. We believe the application of the majority of Medicare revenues threshold criterion, along with the low expenditure threshold, would exclude ESRD laboratories whose Medicare laboratory revenues are mostly derived from the ESRD PPS. However, we would not want to exclude an ESRD laboratory from the definition of applicable laboratory if it receives CLFS revenues greater than the established low revenue threshold. Therefore, we are not developing a low volume threshold specific to ESRD laboratories.

1. Low Expenditure Threshold

As discussed in the proposed rule (80 FR 59393 through 59394), we established a low expenditure threshold to achieve a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a test, and minimizing the reporting burden for laboratories that receive a relatively small amount of revenues under the CLFS. The proposed low expenditure threshold would have required an entity to receive at least $50,000 of its Medicare revenue from the CLFS for a data collection period to be considered an applicable laboratory. We established that threshold based on CY 2013 TIN-level Medicare CLFS claims. We also proposed an initial data collection period of July 1, 2015, through December 31, 2015 (with all subsequent data collection periods being a full calendar year). In conjunction with the shortened initial data collection period, we proposed a $25,000 low expenditure threshold, whereas for all subsequent data collection periods, we proposed a low expenditure threshold of $50,000.

Although we are not revising the low expenditure threshold in response to the public comments we received on the issue, we are revising it in conjunction with our decisions to define applicable laboratory in terms of the NPI rather than the TIN and, as discussed in section III.D., to make the data collection period 6 months rather than a full calendar year.

To establish the new low expenditure threshold amount, we repeated the analysis we used for the proposed rule, but using NPI-level claims data rather than TIN-level claims data. We reviewed Medicare payment amounts from CY 2013 Medicare CLFS claims for physician office laboratories and independent laboratories at the NPI level. We assessed the number of billing physician office laboratories and independent laboratories that would otherwise qualify as applicable laboratories based on the majority of Medicare revenues threshold, but that would be excluded from the definition under various low expenditure revenue thresholds. Consistent with our analysis for the proposed low expenditure threshold, we did not include hospitals whose Medicare revenues were primarily under section 1833(t) of the Act for outpatient services and section 1886(d) of the Act for inpatient services, as these entities are unlikely to meet the definition of applicable laboratory. We found that, with a $25,000 annual revenue threshold, the exclusion of data from physician office laboratories and independent laboratories with total CLFS revenues below that threshold, did not materially affect the quality and sufficiency of the data we needed to set rates. As we found for the proposed rule, we were able to substantially reduce the number of laboratories qualifying as applicable laboratories (that is, approximately 95 percent of physician office laboratories and approximately 55 percent of independent laboratories) while retaining a high percentage of Medicare utilization (that is, approximately 92 percent of CLFS spending on physician office laboratories and approximately 99 percent of CLFS spending on independent laboratories).

Additionally, because we are changing the data collection period from a full calendar year to 6 months in this final rule, we reduced the $25,000 annual low expenditure threshold by 50 percent, which resulted in a $12,500 low expenditure threshold for the 6-month data collection period. Accordingly, any laboratory that would otherwise be an applicable laboratory, but that receives less than $12,500 in CLFS revenues in a data collection period would not be an applicable laboratory (with the exception of single laboratories that offer and furnish ADLTs, which would be considered applicable laboratories only with respect to the ADLTs that they offer and furnish). As discussed previously in this section, we are finalizing the low expenditure threshold criterion as part of the definition of applicable laboratory in § 414.502. In addition, because the initial data collection period will no longer be shorter than subsequent ones, it is no longer necessary for us to apply a different low expenditure threshold to the initial data collection period. Therefore, we are removing the provision in the definition of applicable laboratory that would have distinguished the initial data collection period low expenditure threshold.

As with the proposed low expenditure threshold of $50,000, in determining whether its CLFS revenues in a data collection period are at least $12,500, a laboratory would not include Medicare payments made to hospital laboratories for tests furnished for hospital inpatients or hospital outpatients. In other words, a laboratory would need to determine whether its Medicare revenues from laboratory tests billed on Form CMS 1500 (or its electronic equivalent) and paid under the current CLFS (under section 1833(h) of the Act) and the revised CLFS (under section 1834A of the Act) are at least $12,500 for the data collection period. If a laboratory receives less than $12,500 in Medicare revenues for CLFS services paid on Form CMS 1500 (or its electronic equivalent) during a data collection period, the laboratory would not be an applicable laboratory.

Some laboratories will not know whether they meet the low expenditure threshold, that is, if they receive at least $12,500 in Medicare CLFS revenues in a data collection period, until after the data collection period is over; in that case, they would have to assess their total Medicare CLFS revenues during the 6-month window between the end of the data collection period and the beginning of the data reporting period. However, for many laboratories, it will be clear whether they exceed the low expenditure threshold even before the end of the data collection period. A laboratory would need to reevaluate its status as to the $12,500 low expenditure threshold for each data collection period, that is, every year for ADLTs and every 3 years for all other CDLTs.

B. Definition of Applicable Information

Section 1834A(a)(3) of the Act defines the term "applicable information" as (1) the payment rate that was paid by each private payor for a test during the data collection period, and (2) the volume of such tests for each such payor during the data collection period. Under section 1834A(a)(5) of the Act, the payment rate reported by a laboratory must reflect all discounts, rebates, coupons, and other price concessions, including those described in section 1847A(c)(3) of the Act relating to a manufacturer's average sales price for drugs or biologicals. Section 1834A(a)(6) of the Act states that if there is more than one payment rate for the same payor for the same test, or more than one payment rate for different payors for the same test, the applicable laboratory must report each payment rate and corresponding volume for the test. Section 1834A(a)(3)(B) of the Act provides that applicable information must not include information about a laboratory test for which payment is made on a capitated basis or other similar payment basis during the data collection period.

We proposed to define applicable information in § 414.502 as, for each CDLT for a data collection period, each private payor rate, the associated volume of tests performed corresponding to each private payor rate, and the specific HCPCS code associated with the test, but not information about a test for which payment is made on a capitated basis.

Several terms and concepts in our proposed definition required explanation. First, we addressed the term "private payor rate." The statutory definition of applicable information refers to "payment rate" as opposed to private payor rate; however, we often use payment rate generically to refer to the amount paid by Medicare under the CLFS. For the proposed rule, we believed it could be confusing to the public if we used the term "payment rate" as it related to both applicable information and the amount paid under the CLFS. Because the statute says the payment rate is the amount paid by private payors, we believed "private payor rate" could be used in the context of applicable information rather than payment rate. Therefore, we referred to the private payor rate in regard to applicable information, and we did so even when we were referring to the statutory language that specifically references payment rate. When we used the term "payment rate," unless we indicated otherwise, we were referring to the Medicare payment amount under the CLFS. In our proposed definition of private payor rate, we attempted to be clear that we were limiting the term to its use in the definition of applicable information. We continue to use the term private payor rate with regard to applicable information in this final rule.

Regarding the definition of "private payor rate," the statute indicates that applicable laboratories are to report the private payor rate "that was paid by each private payor," and that the private payor rate must reflect all price concessions. The private payor rate, as we noted previously, is the amount that was paid by a private payor for a CDLT, and we proposed to incorporate that element into our proposed definition of private payor rate. To calculate a CLFS amount, we believed it was necessary to include in private payor rates patient deductible and coinsurance amounts. (Note: In the discussion below, "patient" refers to a privately insured individual while "beneficiary" refers to a Medicare beneficiary.) For example, if a private payor paid a laboratory $80 for a particular test, but the payor required the patient to pay the laboratory 20 percent of the cost of that test as coinsurance, meaning the private payor actually paid the laboratory only $64, the laboratory would report a private payor rate of $80 (not $64), to reflect the patient coinsurance. The alternative would be for private payor rates to not include patient deductibles and coinsurance (such policy would yield $64 in the above example). Thus, the issue of whether to include or exclude patient deductible and coinsurance in the definition of private payor rate has a material effect on the private payor rate and, ultimately, the payment amount determined by CMS. As Medicare generally does not require a beneficiary to pay a deductible or coinsurance on CLFS services, we believed it was important for private payor rates to be reported analogous to how they will be used by CMS to determine the Medicare payment amount for CDLTs under the new payment methodology. For this reason, we proposed that applicable laboratories must report private payor rates inclusive of all patient cost sharing amounts.

With regard to price concessions, section 1834A of the Act is clear that the private payor rate is meant to reflect the amount paid by a private payor less any price concessions that were applied to a CDLT. For example, there may be a laboratory that typically charges $10 for a particular test, but offers a discount of $2 per test if a payor exceeds a certain volume threshold for that test in a given time period. If the payor exceeds the volume threshold, the private payor rate for that payor for that test, taking into account the $2 discount, is $8. The statute lists specific price concessions in section 1834A(a)(5) of the Act—discounts, rebates, and coupons; and in section 1847A(c)(3) of the Act—volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (except for Medicaid rebates under section 1927 of the Act). These lists are examples of price concessions, and, we believed, were not meant to be exhaustive. We indicated that other price concessions that are not specified in section 1834A of the Act might be applied to the amounts paid by private payors, and we would expect those to be accounted for in the private payor rate. Within our definition of private payor rate, we proposed that the amount paid by a private payor for a CDLT must be the amount after all price concessions were applied.

We proposed to codify the definition of private payor rate in § 414.502. Specifically, we proposed that the private payor rate, for applicable information, is the amount that was paid by a private payor for a CDLT after all price concessions were applied, and includes any patient cost-sharing amounts, if applicable.

Next, we addressed the definition of "private payor." Section 1834A(a)(3)(i) of the Act specifies that applicable information is the private payor rate paid by each private payor. Section 1834A(a)(8) of the Act defines private payor as (A) a health insurance issuer and a group health plan (as such terms are defined in section 2791 of the Public Health Service Act), (B) a Medicare Advantage plan under part C, and (C) a Medicaid managed care organization (as defined in section 1903(m) of the Act).

A health insurance issuer is defined in section 2791(b)(2) of the Public Health Service (PHS) Act, in relevant part, as an insurance company, insurance service, or insurance organization (including a health maintenance organization) which is licensed to engage in the business of insurance in a state and which is subject to state law which regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act of 1974 (ERISA)). We incorporated this definition of health insurance issuer into our proposed definition of private payor by referring to the definition at section 2791(b)(2) of the PHS Act.

Section 2791(a)(1) of the PHS Act defines a group health plan, in relevant part, as an employee welfare benefit plan (as defined in section 3(1) of ERISA to the extent that the plan provides medical care and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise. We incorporated this definition of group health plan into our definition of private payor by referring to the definition at section 2791(a)(1) of the PHS Act.

A Medicare Advantage plan under part C is defined in section 1859(b)(1) of the Act as health benefits coverage offered under a policy, contract, or plan by a Medicare+Choice organization under, and in accordance with, a contract under section 1857 of the Act. In the proposed rule we incorporated this definition of Medicare Advantage plan into our definition of private payor by referring to the definition in section 1859(b)(1) of the Act.

A Medicaid managed care organization is defined in section 1903(m)(1)(A) of the Act, in relevant part, as a health maintenance organization, an eligible organization with a contract under section 1876 of the Act or a Medicare+Choice organization with a contract under Medicare Part C, a provider sponsored organization, or any other public or private organization, which meets the requirement of section 1902(w) of the Act and (i) makes services it provides to individuals eligible for benefits under Medicaid accessible to such individuals, within the area served by the organization, to the same extent as such services are made accessible to individuals (eligible for medical assistance under the State plan) not enrolled with the organization, and (ii) has made adequate provision against the risk of insolvency, which provision is satisfactory to the state, meets the requirements under section 1903(m)(1)(C)(i) of the Act (if applicable), and which assures that individuals eligible for benefits under Medicaid are in no case held liable for debts of the organization in case of the organization's insolvency. An organization that is a qualified health maintenance organization (as defined in section 1310(d) of the PHS Act) is deemed to meet the requirements of clauses (i) and (ii). We incorporated this definition of Medicaid managed care organization into our definition of private payor by referring to the definition at section 1903(m)(1)(A) of the Act.

We proposed to codify the definition of "private payor" in § 414.502 as a health insurance issuer, as defined in section 2791(b)(2) of the PHS Act; a group health plan, as defined in section 2791(a)(1) of the PHS Act; a Medicare Advantage plan under Medicare Part C, as defined in section 1859(b)(1) of the Act; or a Medicaid managed care organization, as defined in section 1903(m)(1)(A) of the Act.

Next, section 1834A(a)(3) of the Act requires that applicable information include the private payor rate for each test and the "volume of such tests" for each private payor. Regarding the volume reporting requirement, we are aware that sometimes laboratories are paid different amounts for the same CDLT by a payor. Also, sometimes laboratories are paid different amounts for the same CDLT by different payors. Section 1834A(a)(6) of the Act specifies that an applicable laboratory must report each such private payor rate and associated volume for the CDLT. Accordingly, we proposed that each applicable laboratory must report each private payor rate for each CDLT and its corresponding volume. For example, an applicable laboratory and private payor may agree on a volume discount for a particular test whereby the first 100 tests will be reimbursed at $100. The 101st test (and all thereafter) will be reimbursed at $90. In reporting to CMS, the laboratory would report two different private payor rates for this private payor. The first would be 100 tests at a private payor rate of $100 per test, and the second, $90 for all tests reimbursed thereafter. We proposed to implement the volume reporting requirement by including in the proposed definition of applicable information in § 414.502 that, in addition to "each" private payor rate for "each" CDLT, applicable information is the associated volume of tests performed corresponding to each private payor rate.

In the proposed rule we discussed the need to be able to identify the particular test for which private payor information is being reported. As CLFS tests are identified by HCPCS codes (see 80 CFR 59403 to 59404 for discussion of coding), applicable laboratories will need to report a HCPCS code for each test that specifically identifies the test being reported. We proposed to include in § 414.502 that applicable information includes the specific HCPCS code associated with each CDLT. Some laboratory tests are currently billed using unlisted CPT codes or HCPCS level II miscellaneous/not otherwise classified (NOC) codes. Because NOC codes and unlisted CPT codes do not describe a single test and may be used to bill and pay for multiple types of tests, we would not be able to determine the specific laboratory test corresponding to a reported private payor rate if either was used for reporting. To ensure that applicable laboratories do not report applicable information with a NOC code or an unlisted CPT code, we also proposed to define "specific HCPCS code" in § 414.502 as a HCPCS code that does not include an unlisted CPT code, as established by the American Medical Association, or a NOC code, as established by the CMS HCPCS Workgroup. Therefore, data on tests that are billed using unlisted CPT codes or NOC codes would not be considered applicable information and would not be reported.

Finally, the statute specifies that applicable information does not include certain information listed in section 1834A(a)(3)(B) of the Act—information for a laboratory test for which payment is made on a capitated basis or other similar payment basis during the data collection period. A capitated payment is made for health care services based on a set amount for each enrolled beneficiary in the plan for a given period of time, regardless of whether the particular beneficiary receives services during the period covered by the payment. Payment is typically made on a capitated basis under a managed care arrangement. As there is no way to determine payment specifically for a given test, it cannot be reported as applicable information. Therefore, we proposed to specify in the definition of applicable information in § 414.502 that the term does not include information about a test for which payment is made on a capitated basis. We stated that we do not believe providing a discount based on volume of tests furnished is an example of a payment made on a capitated basis or other similar payment basis.

A discussion of the public comments we received on the definition of applicable information and our responses to those comments appears below.

Comment: Many commenters requested that we exclude private payor rates from the definition of applicable information that would be administratively burdensome, if not impossible, for applicable laboratories to report to CMS. Specifically, the commenters suggested that private payor rates that would not have any bearing on establishing the weighted median private payor payment rates, and would otherwise be immensely burdensome for laboratories to report, should be excluded from the definition of applicable information. The commenters contended that not including certain information as applicable information would not have a material effect on the weighted median private payor payment rates and would reduce the burden on applicable laboratories. They provided the following examples of payments that should be excluded from the definition of applicable information and therefore from reporting, if the laboratories so chose:

- Hard copy (manual) remittances where HCPCS-level payment data are not captured or the formatting of the hard copy remittance advice is not conducive to optical character recognition (OCR) scanning;
- Manual remittances where the payor has grouped test-level payments into an encounter-level (claim-level) payment;
- Payments that were made in error, which are often not corrected until months after the incorrect payment was received;
- Bulk settlements;
- Payments that include post-payment activity such as recoupments;
- Payments from secondary insurance payors;
- Payments that do not reflect specific HCPCS code-level amounts; and
- Other similar payments.

The commenters requested that we permit some measure of flexibility for applicable laboratories to exclude reporting the aforementioned items from applicable information where the administrative burden of collecting and reporting applicable information exceeds any potential to influence the final payment rate. To that end, the commenters requested that we issue subregulatory guidance after publication of the final rule to specify the information that laboratories may exclude from reporting.

Response: As discussed in the proposed rule (80 FR 59394), we proposed to define applicable information to mean each private payor rate for each CDLT in a data collection period, the associated volume of tests performed corresponding to each private payor rate, and the specific HCPCS code associated with the test, but not information about a test for which payment is made on a capitated basis. We proposed that private payor rate would mean, in part, "the amount that was paid" by a private payor.

First, the commenters' specific requests that certain information be excluded from the definition of applicable information indicate to us that we need to provide clarification about what we meant by the term "paid" in the proposed definition of private payor rate. We clarify here that an amount has been paid if the laboratory received final payment for the test. Many of the items commenters requested to be excluded would not be considered applicable information because final payment would not have been made for the test. For instance, a private payor pays a laboratory for a test, but subsequent post-payment activities may change that initial payment amount. Some examples of post-payment activity that could change the initial payment amount are the correction of an initial payment made in error or recoupment of payment. Where those types of activities result in a final payment, the resulting payment amount would be considered for purposes of the private payor rate if it is made to the laboratory in the data collection period. For example, if an initial claim was paid in error 3 months before a data collection period and then corrected, with final payment being made by the private payor during the data collection period, the final corrected payment amount for the test would be considered for purposes of the private payor rate. If a test is performed during a data collection period, but a final payment is not made until after the data collection period, that payment amount would not be a private payor rate for purposes of applicable information and, therefore, would not be reported to CMS. Final payments from secondary insurance payors would also be considered in calculating private payor rates if the final payment was made during the data collection period.

Second, commenters asked whether payment rates can be excluded from the definition of applicable information if the payment does not reflect specific HCPCS code-level amounts. In the proposed rule (80 FR 59396), we explained that we need to be able to identify the particular test for which private payor information is being reported. Therefore, we proposed to require that applicable information includes the specific HCPCS code associated with each CDLT to prevent private payor rates corresponding to a HCPCS level II/not otherwise classified (NOC) code or an unlisted CPT code from being reported. Accordingly, if a laboratory cannot correlate a private payor payment amount to a specific HCPCS code, that amount is not a private payor rate for purposes of applicable information.

Third, commenters asked about excluding from applicable information manual remittances where the payor has grouped test-level payments into an encounter (claim-level) payment. The proposed rule specified that, for each CDLT, the associated volume of tests performed corresponding to each private payor rate is a component of the definition of applicable information. Where the associated volume of tests performed corresponding to each private payor rate cannot be discerned by a laboratory from the private payors' remittance, those payment amounts would not be considered applicable information and should not be reported to CMS. Therefore, where a private payor groups test-level payments into a claim-level payment, instead of by individual HCPCS code, those rates would not be applicable information.

Commenters also asked that we allow stakeholders to decide whether the burden of collecting and reporting certain payment rates outweighs the potential influence those rates would have on final payment rates and, when that is the case, stakeholders would not have to report it as applicable information. We cannot permit stakeholders to exercise that discretion. The statute is clear that applicable information, which is used to set CLFS payment amounts, must be reported for applicable laboratories for a data collection period, and it defines applicable information, in part, as the payment rate that was paid by each private payor for the test during a data collection period and the volume of such tests for each such payor for the data collection period. As such, we believe the statute does not support selective reporting of applicable information for applicable laboratories. If the laboratory meets the definition of applicable laboratory, the applicable information for that laboratory must be reported.

Comment: Many commenters raised questions about a variety of other issues regarding the definition of applicable information. They stated that the proposed rule does not clearly specify the dates that apply to private payor rates. For example, commenters asked whether private payor rate information collected during the data collection period is based on the date of payment, date of service, date of claim submission, or date of denial. The commenters stated that if the date of service is the controlling date, claims for laboratory services furnished during the data collection period may not be paid before the data collection period ends, which would mean the payment amounts would not qualify as private payor rates. These same commenters questioned whether denials, which they referred to as "zero payments," are to be excluded from the data set reported to CMS. Many commenters requested clarification as to how to handle claims undergoing an appeal. Commenters also requested clarification as to whether the private payor rates collected include non-contracted amounts for out-of-network laboratories or services.

Response: As discussed in response to the previous comment, final payment must be made by the private payor for a laboratory test(s) during the data collection period for the rate to be considered in calculating a private payor rate. If the date of the final payment for a CDLT falls within a data collection period, the payment rate would be considered to have been paid for purposes of the definition of private payor rate.

Where a laboratory test claim is still under review by the private payor or is under appeal during a data collection period, the amount that has already been paid would not be considered a final payment rate and would therefore not be used to determine a private payor rate. Payment rates for claims under appeal would only be private payor rates if the final payment amount is determined and paid during the data collection period. For example, if a laboratory filed an appeal for a test furnished prior to a data collection period, and the appeal was resolved so that final payment for the test was made during the data collection period, the final rate paid would be used to calculate the private payor rate. However, if the appeal was settled during the data collection period, but final payment was not made by the private payor until after the data collection period, the payment amount could not be used for a private payor rate and would therefore be excluded from applicable information.

Some commenters asked whether denials, which they referred to as zero payments, would need to be reported as applicable information because no private payor payment amount was made for the laboratory test(s). We assume commenters are suggesting that when a claim is denied, the payment amount for the test could be said to be zero dollars, so commenters want to know if, in those instances, they should report zero dollars as the private payor rate. Laboratories should not report zero dollars for CDLTs where a private payor has denied payment within a data collection period. We are revising the definition of private payor rate in § 414.502 to specify that it does not include information about denied payments.

Finally, in response to the commenters' request for clarification as to whether private payor rate includes non-contracted amounts for out-of-network laboratories or services, we clarify that applicable information includes private payor rates for out-of-network laboratories, as long as the final payment for the laboratory test was made by the private payor during the data collection period. As the statutory definition of applicable information does not distinguish between contracted and non-contracted amounts paid by private payors, we believe it is appropriate for the private payor rate to include non-contracted amounts paid to laboratories.

We are modifying the definition of applicable information in § 414.502 to clarify that, with respect to each CDLT, applicable information includes each private payor rate for which final payment has been made in the data collection period. We are also renumbering the provisions within the definition to make the requirements clearer; these are non-substantive changes that do not affect the final policy. In addition, we are modifying the definition of private payor rate in § 414.502 to clarify two points: (1) The private payor rate is the "final amount" that was paid by a private payor for a CDLT and; (2) as noted above, the private payor rate does not include information about denied payments.

Comment: Many commenters agreed with our proposal to include patient deductible and coinsurance amounts as part of the definition of private payor rate and our rationale for doing so. The commenters encouraged us to finalize our proposal to require applicable laboratories to report private payor rates that include patient cost sharing amounts.

Response: We agree with the commenters and are finalizing our proposed policy.

Comment: Two commenters stated that beneficiary cost sharing is frequently used to mean copayments and coinsurance, and recommended that we clarify our intent that private payor rate includes any patient cost sharing and deductible amounts if applicable.

Response: As discussed in the proposed rule (80 FR 59395), Medicare generally does not require a beneficiary to pay a deductible or coinsurance amount for services paid under the CLFS, and we believe it is important that private payor rates be reported analogous to how they will be used to determine the Medicare payment amount for laboratory tests under the new CLFS methodology. Therefore, we proposed that private payor rate includes all patient cost sharing amounts. For purposes of reporting applicable information under the CLFS, we clarify that private payor rate includes any patient cost sharing amounts required by private payors, including patient deductible amounts, coinsurance amounts (that is, the percentage of the fee schedule amount a private payor requires the patient to pay for a given laboratory test), and copayment amounts (that is, the specific dollar amount a private payor requires the patient to pay for a given laboratory test).

Comment: One commenter agreed with our proposal to include "front-end concessions" such as volume thresholds in private payor rates. However, the commenter stated that under the OIG's 1994 Special Fraud Alert and Medicare Claims Guidelines, providers, practitioners, or suppliers may forgive the deductible and copayments in consideration of a particular patient's financial hardship. The commenter believes that when the laboratory provides this type of "one-off financial hardship" discount, such concession should not be included in the private payor rate.

Response: Section 1834A(a)(5) of the Act requires the private payor rate to reflect all discounts, rebates, coupons, and other price concessions, including those described in section 1847A(c)(3) of the Act. Accordingly, we proposed that the private payor rate is, among other things, the amount that was paid by a private payor for a CDLT after all price concessions are applied.

We are clarifying here that the price concessions to be applied are only those applied by the private payor. We do not intend that concessions applied by a laboratory, such as, for example, the waiver of patient coinsurance, copayments, or deductibles due to a patient's financial hardship, would be a price concession for purposes of the definition of private payor rate. The statute envisions that CLFS payment rates under the new system are based on the rates paid by private payors. Although laboratories may provide concessions to patients, we do not believe it is appropriate to factor those concessions into a system that is required to be based on the rates paid by private payors. We understand, however, that we may have created some confusion about which price concessions are to be applied and which are not. Unfortunately, we provided an example in the proposed rule of a discount provided by a laboratory, as opposed to a private payor, that would be considered to be a price concession. This example did not reflect our intent that, for the private payor rate, only price concessions made by the private payor are to be applied.

To be clear, concessions applied by a laboratory are not price concessions for purposes of the private payor rate. To clarify that only private payor price concessions apply in calculating the private payor rate and not those applied by the laboratory, we are modifying the definition of private payor rate in § 414.502 to indicate that, for purposes of applicable information, private payor rate is the final amount that was paid by a private payor for a CDLT after all private payor price concessions are applied, and does not include price concessions applied by a laboratory.

Comment: Many commenters raised questions as to whether private payor rates for laboratory tests paid only on the PFS should be reported, and requested that we publish a list of HCPCS codes for which we expect applicable laboratories to report applicable information.

Response: Only private payor payment rates for CDLTs paid for under the CLFS are considered for private payor rates. The payment rates for laboratory tests paid only under the PFS, and not under the CLFS, would not be private payor rates and should not be reported as applicable information. We will publish a list of HCPCS codes on the CLFS Web site for which applicable laboratories must report private payor rates as part of subregulatory guidance.

Comment: One commenter noted that the proposed rule only defines applicable information in terms of private payor rates. The commenter stated that if Medicare payments are not included, we would be neglecting to use the majority of payment rate information in determining the weighted median private payor payment amounts under the new CLFS.

Response: Section 1834A(a)(3) of the Act defines applicable information as the payment rate that was paid by each private payor, and section 1834A(a)(8) defines private payors to include health insurers, group health plans, Medicare Advantage plans under part C, and Medicaid managed care organizations. Therefore, we clarify that applicable information would include Medicare data to the extent it is collected from Medicare Advantage plans and reported to CMS.

Comment: One commenter suggested that the proposed regulations text be revised to refer to applicable "rate" information instead of applicable information.

Response: Section 414.502 defines applicable information as each private payor rate, the associated volume of tests performed corresponding to each private payor rate, and the specific HCPCS code associated with the test. We believe this is sufficient specificity for the industry to understand what applicable information is without adding the word "rate" to the term.

C. Definition of Advanced Diagnostic Laboratory Tests (ADLTs) and New ADLTs

The statute applies different reporting and payment requirements to ADLTs than to other CDLTs, and further distinguishes a subset of ADLTs called "new ADLTs." In this section, we discuss our definitions for the terms "advanced diagnostic laboratory test" and "new advanced diagnostic laboratory test."

1. Definition of ADLT

Section 1834A(d)(5) of the Act defines an ADLT as a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and that meets one of the following criteria: (1) The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result; (2) the test is cleared or approved by the FDA; (3) the test meets other similar criteria established by the Secretary. Sections 1834A(d)(1) and (2) of the Act recognize special reporting and payment requirements for ADLTs for which payment has not been made under the CLFS prior to April 1, 2014 (PAMA's enactment date). In establishing a regulatory definition for ADLT, we considered each component of the statutory definition at section

1834A(d)(5) of the Act, and how we interpreted and incorporated key statutory terms and phrases.

We believe that, by including these provisions for ADLTs, the statute seeks to establish special payment status for tests that are unique and are provided only by the laboratory that developed the test, or a subsequent owner of that laboratory. In other words, we view the statute as intending to award special payment status to the one laboratory that is expending the resources for all aspects of the test—developing it, marketing it to the public, performing it, and selling it. It is with this understanding that we developed our proposed policies for defining ADLTs.

First, to be an ADLT, a test must meet the requirements specified in the first part of the definition at section 1834A(d)(5) of the Act, that is, it must be a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner). For the meaning of "single laboratory," we believed the statute intends to ensure that we grant ADLT status to the one laboratory that offers and furnishes the particular test, to the exclusion of all other laboratories. To ensure this is the case, we proposed to require the laboratory to be a facility with a single CLIA certificate as described in § 493.43(a) and (b) because we believed, in most instances, the laboratory's single CLIA certificate would correspond to one laboratory location or facility. Under our proposal, an entity with multiple CLIA certificates would not be a single laboratory. For example, a test offered by a health system consisting of multiple entities, including physician offices and independent laboratories, and that has multiple CLIA certificates associated with its multiple testing locations, would not be eligible for ADLT status, even if the test met all other ADLT criteria. Section 493.43(b) includes several narrow exceptions for certain types of laboratories that may have multiple locations.[1] We stated that we did not believe those exceptions would apply to most or all laboratories seeking ADLT status for a given test and, even if they did, we did not believe those particular exceptions would undermine our effort to identify the single laboratory offering and furnishing the ADLT.

Next, the statute directs that the test must be "offered and furnished" by a laboratory seeking ADLT status for the test. It also requires that the test be "not sold for use by a laboratory other than the original developing laboratory." We interpreted the original developing laboratory referenced in the statute to be the same laboratory that offers and furnishes the test. This interpretation was consistent with our understanding that the statute intends for special payment status to be awarded to the one laboratory that is expending the resources for all aspects of the test. Within the two requirements—(1) that a laboratory seeking ADLT status must offer and furnish the test and (2) that the test is not sold for use by a laboratory other than the original developing laboratory—there were several components for us to parse, and we did so consistent with our view of the statutory intent. First, we stated that we believed a laboratory offers and furnishes a test when it markets and performs the test. The laboratory that markets and performs the test must also be the only one to sell it, that is, to receive remuneration in exchange for performing the test. In addition, we believed that laboratory must also be the one that developed the test, which means the laboratory designed it. We are aware that, in certain circumstances, a referring laboratory may bill for a test under section 1833(h)(5)(A) of the Act. The referring laboratory is a laboratory that receives a specimen to be tested and refers it to another laboratory, the reference laboratory, to perform the test. We explained that, in these situations, because the reference laboratory performed the test, it would be the laboratory that offered and furnished the test for purposes of the ADLT definition.

Accordingly, under our proposal, only one laboratory could design, market, perform, and sell the test. If more than one laboratory engages in any of those activities, the test would not meet the criteria to be an ADLT. Under our proposal, we would not expect to see more than one applicable laboratory report applicable information for a given ADLT.

Next, the statute permits a successor owner to the original developing laboratory to sell the test without disqualifying the test from ADLT status. We proposed to define successor owner as a laboratory that has assumed ownership of the original developing laboratory, and meets all other aspects of the ADLT definition (except for being the original developing laboratory). This means the successor owner is a single laboratory that markets, performs, and sells the ADLT.

In considering how to define successor owner, we looked to our regulations at § 489.18(a), which describe what constitutes a change of ownership for Medicare providers. Although laboratories are suppliers and not providers, we believed the language in this regulation appropriately applied to the wide range of potential changes in ownership for laboratories. Specifically, we proposed to incorporate the scenarios described in § 489.18(a) as discussed in the proposed rule, 80 FR 59397, as follows. A successor owner, for purposes of an ADLT, would mean a single laboratory that has assumed ownership of the laboratory that designed the test through any of the following circumstances:

- Partnership. In the case of a partnership, the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable state law, constitutes change of ownership.
- Unincorporated sole proprietorship. Transfer of title and property to another party constitutes change of ownership.
- Corporation. The merger of the original developing laboratory corporation into another corporation, or the consolidation of two or more corporations, including the original developing laboratory, resulting in the creation of a new corporation constitutes change of ownership. However, a transfer of corporate stock or the merger of another corporation into the original developing laboratory corporation does not constitute change of ownership.
- Leasing. The lease of all or part of the original developing laboratory facility constitutes change of ownership of the leased portion. In the case of a lease, all of or part of the original developing laboratory is leased by the owner(s) of the original developing laboratory to another entity who takes over the continued production of the test, and the owner(s) of the original developing laboratory becomes the lessor of the laboratory where it formerly provided laboratory tests. In this situation, there would be a change of ownership of the leased portion of the laboratory, and the lessee would become the successor owner that could be paid for performing an ADLT, provided the test meets all other criteria for being an ADLT.

As we noted, the successor owner would need to be a single laboratory and meet all other aspects of the ADLT definition. For example, under our proposal, if an original developing laboratory corporation is merged into another laboratory corporation that has multiple CLIA certificates, while the test would still be a CDLT, it would no longer be considered an ADLT. Under our proposal, we expected a laboratory that obtains CMS approval of ADLT status for a test to maintain documentation on changes of ownership with transfer of rights to market, perform, and sell the ADLT to support correct claims submission and payment. We proposed to define the terms "single laboratory" and "successor owner" in § 414.502.

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[1] Section 493.43(b) includes the following exceptions: (1) Laboratories that are not at a fixed location; (2) not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing; and (3) laboratories that are within a hospital that are located at contiguous buildings on the same campus and under common direction.

Next, in addition to meeting the first part of the ADLT definition at section 1834A(d)(5) of the Act, the statute requires that an ADLT must meet one of the criteria described in paragraphs (5)(A), (5)(B), or (5)(C). Criterion A of section 1834A(d)(5) of the Act states that the test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result. We interpreted this provision to require that the test analyze, at a minimum, biomarkers of DNA or RNA. Tests that analyze nucleic acids (DNA or RNA) are molecular pathology analyses. Therefore, we proposed that, under criterion A, a test must be a molecular pathology analysis of DNA or RNA. Examples of such tests include those that analyze the expression of a gene, the function of a gene, or the regulation of a gene. The statute also requires that the test analyze "multiple" biomarkers of DNA, RNA, or proteins. Therefore, we stated that an ADLT might consist of one test that analyzes multiple biomarkers or it might consist of multiple tests that each analyzes one or more biomarkers.

That the analysis of the biomarkers must be "combined with a unique algorithm to yield a single patient-specific result" indicated to us that the algorithm must be empirically derived, and that the ultimate test result must be diagnostic of a certain condition, a prediction of the probability of an individual developing a certain condition, or the probability of an individual's response to a particular therapy. Furthermore, the statute requires the result to be a single patient-specific one, so we proposed that the test must diagnose a certain condition for an individual, or predict the probability that a specific individual patient will develop a certain condition(s) or respond to a particular therapy. We also proposed that the test must provide new clinical diagnostic information that cannot be obtained from any other existing test on the market or combination of tests (for example, through a synthesis of the component molecular pathology assays included in the laboratory test in question). We considered requiring that a new ADLT be clinically useful, as well as new, but decided against such a policy due to statutory limitations. These proposed policies for implementing criterion A were based on our view that ADLTs that meet the criterion are innovative tests that are new and different from any prior test already on the market and provide the individual patient with valuable genetic information to predict the trajectory of the patient's disease process or response to treatment of the patient's disease that could not be gained from another test or tests on the market. Finally, we stated that we expected an ADLT could include assays in addition to the biomarker assay(s) described above. For example, in addition to an analysis of a DNA biomarker, an ADLT might also include a component that analyzes proteins. We would not disqualify a test from ADLT status consideration if that is the case. In summary, we proposed that to qualify as an ADLT under criterion A of section 1834A(d)(5) of the Act, a test: (i) Must be a molecular pathology analysis of multiple biomarkers of DNA, or RNA; (ii) when combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies); (iii) provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and (iv) may include other assays. We included this proposed requirement in paragraph (1) of the ADLT definition in § 414.502.

Criterion B of section 1834A(d)(5) of the Act states that the test is cleared or approved by the FDA. The FDA considers CDLTs to be medical devices, and has two main application processes for clearing and approving medical devices. To receive FDA clearance to market a new device, a Premarket Notification submission, also referred to as a 510(k), is submitted to FDA for review at least 90 days before introducing, or delivering for introduction, the device into interstate commerce. Before FDA can clear a 510(k) and allow a device to be commercialized, the 510(k) submitter must demonstrate that their medical device is "substantially equivalent" to a device that is legally marketed for the same intended use and for which a Premarket Approval Application (PMA) is not required. A request for FDA approval of a device is typically submitted through a PMA, which is the most stringent type of device marketing application required by FDA. A PMA refers to the scientific and regulatory review necessary to evaluate the safety and effectiveness of devices that have not been found to be substantially equivalent through the 510(k) [Premarket Notification] process or devices for which insufficient information exists to determine that general controls either alone (Class I) or together with special controls (Class II) would provide a reasonable assurance of their safety and effectiveness. To obtain FDA approval of a device, an applicant must submit a PMA which includes valid scientific evidence to assure that the device is safe and effective for its intended use(s). We further noted that FDA regulations or orders exempt many Class I and certain Class II devices from premarket notification and allow them to be legally marketed immediately without premarket clearance. Since criterion B of section 1834A(d)(5) of the Act requires FDA approval or clearance, we stated that we did not intend for this criterion to cover any devices that are, by regulation or order, exempt from premarket notification and that have not received FDA approval or clearance. We proposed that a laboratory test can be considered an ADLT if it is cleared or approved by the FDA and meets all other aspects of the ADLT definition. Under criterion B, laboratories would have to submit documentation of their FDA clearance or approval for the test. We stated that this process would be outlined through subregulatory processes prior to January 1, 2016.

To implement criteria A and B, we stated that we would establish guidelines for laboratories to apply for ADLT status and submit documentation to support their application. For example, we indicated that if our proposed definition of criterion A is finalized, laboratories would have to submit to CMS evidence of their empirically derived algorithms and show how their test provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests. As we noted in section II.F. of the proposed rule (80 FR 59402), section 1834A(a)(10) of the Act provides for confidentiality of the information disclosed by a laboratory under section 1834A(a) of the Act. As this statutory provision is limited to "this section" (that is, section (a)), we believed it does not apply to section (d) of section 1834A of the Act, which relates to information provided to the Secretary to determine whether a test is an ADLT. While we stated that we do not expect to make information in an ADLT application available to the public, that information is not explicitly protected from disclosure under the confidentiality provisions of the statute, nor is it explicitly protected from disclosure in response to a Freedom of Information Act (FOIA) request, as is information disclosed by a laboratory under section (a), per section 1834A(a)(11) of the Act. However, we noted that FOIA includes an exemption for trade secrets and commercial or financial information obtained from a person that is privileged or confidential. An ADLT applicant should be aware that information in an ADLT application may not be protected from public disclosure even if it is marked as confidential and proprietary. We indicated that we could not guarantee information marked as proprietary and confidential will not be subject to release under FOIA. While a party may mark information as confidential and proprietary, the information may be subject to disclosure under FOIA unless, consistent with FOIA exemption (b)(4), the information relates to trade secrets and commercial or financial information that is exempt from disclosure. The ADLT applicant would need to substantiate this confidentiality by expressly claiming substantial competitive harm if the information is disclosed and demonstrating in a separate statement how the release would cause substantial competitive harm pursuant to the process in E.O.12600 for evaluation by CMS (please see 80 FR 59402 through 59403 for further discussion of the confidentiality and public release of data).

Criterion C of section 1834A(d)(5) of the Act gives the Secretary the authority to establish and apply other similar criteria by which to determine that a test is an ADLT. We did not propose to exercise this authority; however we indicated that if we do so in the future, it would be through notice and comment rulemaking.

2. Definition of New ADLT

Section 1834A(d) of the Act is titled "Payment for New Advanced Diagnostic Laboratory Tests." As previously discussed in this section, section 1834A(d)(1)(A) of the Act provides special payment rules for ADLTs for which payment has not been made under the CLFS prior to April 1, 2014, the enactment date of PAMA. Section 1834A(i) of the Act, titled "Transitional Rule," provides that during the period beginning on April 1, 2014, PAMA's enactment date, and ending on December 31, 2016, for ADLTs paid under Medicare Part B, the Secretary shall use the methodologies for pricing, coding, and coverage in effect on the day before April 1, 2014, which may include crosswalking or gapfilling methods. We interpreted section 1834A(i) of the Act to mean that we must use the current CLFS payment methodologies for ADLTs that are furnished between April 1, 2014, and December 31, 2016.

Accordingly, we proposed to define a new ADLT as an ADLT for which payment has not been made under the CLFS prior to January 1, 2017. Any ADLT paid for under the CLFS prior to January 1, 2017, would be an existing ADLT and would be paid in accordance with the current regulations at 42 CFR part 414, subpart G, including gapfilling and crosswalking methodologies. In other words, there would be no new ADLTs until January 1, 2017, and they would be first paid on the CLFS using the payment methodology for new ADLTs proposed in § 414.522. We proposed to codify the definition of "new ADLT" at § 414.502 to mean an ADLT for which payment has not been made under the CLFS prior to January 1, 2017.

A discussion of the public comments we received on the definitions of ADLT and new ADLT and our responses to those comments appears below.

Comment: A few commenters disagreed with our proposal to require an ADLT to be "marketed and performed" by a single laboratory. The commenters noted that in defining an ADLT, the statute requires the test be "offered and furnished" by a single laboratory, and that requiring activities such as marketing and performing the test would go beyond the intent of Congress and place undue restrictions on the normal business practices of ADLT laboratories. The commenters stated that "offered and furnished," when read in the context of the statutory definition of an ADLT, indicates that the single laboratory furnishes the test and does not sell it as a "kit" to other laboratories for those laboratories to offer and furnish. The commenters also explained that a small ADLT laboratory may partner with larger laboratories to provide marketing support while still performing and billing for its tests because of resource constraints. In this scenario, the test would be offered and furnished by a single laboratory, but it may not qualify for ADLT status under the proposed requirement that the single laboratory must market and perform the test. The commenters contend that the words "offered and furnished" are sufficiently clear and well understood in the Medicare program and that CMS does not need to complicate the definition by redefining it as "marketed and performed." Thus, the commenters recommended using the statutory terms "offered and furnished" instead of "marketed and performed."

Response: We agree with commenters that our definition of single laboratory should not preclude a test that would otherwise qualify as an ADLT from being an ADLT simply because the single laboratory relies on a third party to market the test, although we do not think our definition would necessarily do that. Even though a single laboratory may hire another entity to market the test, the single laboratory would still be the entity expending the resources for the test.

In the proposed rule, we explained that we considered "marketing" to be an appropriate illustration of how we interpreted the term "offer." Nonetheless, we agree that some marketing activities, such as developing and implementing a promotional strategy, may go beyond "offering" a test. What we were attempting to achieve with our proposal that the single laboratory must be the only laboratory to market and perform the test, was to ensure that the single laboratory was the entity expending the resources for all aspects of the test, in other words, the entity responsible for administering all aspects of the test. We are using the term "offer" rather than "market" in this final rule because we are convinced by commenters that the terms are not synonymous and, in fact, marketing goes beyond the scope of offering. If a laboratory offers a test, it is presenting the test for sale, which is consistent with our view that a single laboratory is the entity expending the resources and is responsible for administering all aspects of the test.

In addition, we used the term "performed" in the proposed rule to illustrate what we believe it means for a laboratory to furnish a test. While it is important for the industry to know how we interpret the term "furnish," we understand the industry prefers we use the term "furnish" in the regulatory definition of ADLT. Therefore, we are revising our proposed definition of ADLT in § 414.502 to include the statutory terms "offered and furnished" rather than "marketed and performed."

Comment: Several commenters did not agree with our proposal to define a single laboratory as a facility with a single CLIA certificate. The commenters stated that our proposed definition of "single laboratory" does not comport with how laboratories operate, and would be an insurmountable barrier for many laboratories whose tests Congress meant to include as ADLTs. They explained that one laboratory may expend resources for all aspects of the test, but that laboratory does not necessarily hold only one CLIA certificate. For example, a laboratory may have multiple sites, each with its own CLIA certificate, but furnishes the ADLT at only one of those sites. Or, due to higher than expected demand for its testing, a laboratory may have to open a new laboratory facility in which to perform testing, and that second facility would be required to obtain its own CLIA certificate because of its different mailing address or location. The commenters stated that, as long as the offering and furnishing laboratory does not sell the test for use by another laboratory, then the number of CLIA certificates the entity holds should not be relevant to whether a test can qualify as an ADLT. Therefore, they recommended that, for purposes of an ADLT, the definition of "single laboratory" be revised to mean a laboratory and its parent corporation, wholly-owned subsidiaries, and other entities under common ownership, as applicable.

Response: After reviewing the public comments on this issue, we agree that defining single laboratory by requiring the laboratory to administer every aspect of the test—offer, furnish, develop, and sell—at only one physical location, is inconsistent with how laboratories are structured and how they operate. As noted by the commenters, a corporate entity may consist of multiple laboratories and other entities under common ownership that have different functions, for instance a laboratory that offers and furnishes tests and other entities that perform research and development activities. Additionally, we believe it is possible that limiting the definition of single laboratory to a facility with a single CLIA certificate could, in some instances, impede beneficiary access to unique, innovative laboratory tests.

For these reasons, we are not adopting our proposal to define single laboratory as a facility with a single CLIA certificate. For purposes of an ADLT, we are revising the definition of single laboratory to mean a laboratory as defined in § 493.2 which furnishes the test, and that may also design, offer, and sell the test. The definition also includes the entities that own the laboratory or that the laboratory owns, which may design, offer, and sell the test; this includes other laboratories that may be owned by the single entity.

We believe this revised approach will allow a corporate entity that owns multiple laboratories to furnish a new ADLT at each laboratory site, and will enable other parts of the single laboratory organization to be involved with aspects of the ADLT such as research and development. It will also allow an original developing laboratory that meets the definition of a single laboratory to continue to be a single laboratory if it chooses to expand its organization by acquiring new laboratory sites to meet increased demand for laboratory testing. Revising the definition of single laboratory to allow multiple laboratories located in different locations throughout the country, under common ownership, to furnish the test could also improve beneficiary access to innovative laboratory tests.

Although our revised definition will enable parts of the single laboratory organization other than its component laboratories to assume responsibilities such as developing (as we discuss above, we believe when a laboratory develops a test, it means the laboratory designs it), offering, and selling the test, only the laboratory parts of the single laboratory organization may perform the test. Therefore, our revised definition specifies that only laboratories, as defined in § 493.2, may furnish the ADLT.

We are revising the definition of single laboratory in § 414.502 to indicate that a single laboratory, for purposes of an ADLT, means the laboratory, as defined in § 493.2, which furnishes the test, and that may also design, offer, or sell the test and the entity that owns the laboratory and the entity that is owned by the laboratory which may design, offer, or sell the test.

Additionally, as discussed previously in this section, we proposed that a successor owner for purposes of an ADLT, means a single laboratory that has assumed ownership of the laboratory that designed the test through any of the following circumstances: Partnership; unincorporated sole proprietorship; corporation; or leasing. Under our revised definition of single laboratory, because each successor owner is an entity that assumes ownership of a single laboratory, the successor owner becomes the owner of the entire single laboratory organization, that is, the laboratory and the other entities the laboratory owns or is owned by. For example, if the single laboratory owns multiple laboratories and other entities, then a change in partnership or sole proprietorship, as described in the definition of successor owner, would have to apply to the entire single laboratory organization to qualify as successor ownership. In the case of a merger of the single laboratory into another corporation or its consolidation with two or more corporations that results in a new corporation, the entire single laboratory organization would need to be included in the corporate merger to qualify as successor ownership.

For changes in ownership resulting from leasing, we proposed (80 FR 59397) that the lease of all or part of the single laboratory organization would constitute a change in ownership of the leased portion. However, we cannot reconcile leasing a portion of a single laboratory with our final policy that a single laboratory includes the laboratory and the other entities that own or are owned by the laboratory. Therefore, we are removing leasing from the definition of successor owner as a circumstance under which there can be a successor owner.

In addition, in the proposed rule we indicated that a successor owner for purposes of an ADLT means a single laboratory that has assumed ownership of the laboratory that designed the test. We recognize that successor ownership is not limited to just the successor of the original developing laboratory. There can be successor owners to successor owners. Therefore, we are revising the definition of successor owner to clarify, for purposes of an ADLT, a successor owner means a single laboratory that has assumed ownership of the single laboratory that designed the test or of the single laboratory that is a successor owner to the single laboratory that designed the test, through any of the following circumstances:

(1) Partnership—the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable state law;

(2) Unincorporated sole proprietorship—the transfer of title and property to another party;

(3) Corporation—the merger of the single laboratory corporation into another corporation, or the consolidation of two or more corporations, including the single laboratory, resulting in the creation of a new corporation. We also specify that a transfer of corporate stock or the merger of another corporation into the single laboratory corporation does not constitute change of ownership.

Comment: One commenter stated that the proposed definition of a "successor owner" does not include a laboratory that acquires the license to an ADLT that was "discovered" by a different entity. Specifically, the commenter explained that a number of ADLTs may be discovered by academic researchers who own the intellectual property rights to a test such as a multi-analyte assay with algorithmic analysis. In these instances, the intellectual property rights would belong to the sponsoring institution and in many cases, the institution is incapable of further developing and validating the test or making it commercially available to the general public, or does not wish to do so. Some of the reasons given by the commenter for why the academic institution may not bring the test to market include, lack of capital, lack of support from the institution's laboratory or other facilities, and lack of infrastructure. In such cases, the commenter stated, the institution would license the intellectual property rights to another entity that develops the test for commercialization, and performs clinical trials to demonstrate analytic and clinical validity and clinical utility. The commenter contends that, even though this entity would only be a licensee, it is responsible for developing and validating the test in its own laboratory and therefore should be viewed as the successor owner for purposes of the definition of ADLT. Further, the commenter urged CMS to confirm that, a laboratory that obtains the exclusive license to the intellectual property rights for one or more uses of a test from the laboratory that "discovered" the test is also a successor owner.

Response: An academic institution that creates a test but does not fully develop it for use by the public would not be considered the original developing laboratory if it is not a laboratory under § 413.2, and if it does not design, sell, offer, and furnish the test, it would not meet the requirements of a single laboratory in the definition of ADLT.

The commenter describes a situation wherein an academic institution licenses the intellectual property to another entity that further develops the test for commercialization. We believe that by "discovering" the test, the academic institution partially develops the test. For instance, a laboratory that purchases the intellectual property of the test may rely on the academic institution to develop a method the test utilizes or a particular reagent the academic institution has patented. In such situations, the laboratory that purchased the intellectual property would not be expending its own resources on all aspects of the development of the test and therefore, could not be considered an original developing laboratory of the test. It also could not be a successor owner if the academic institution is not the original developing laboratory or a single laboratory. As such, the test would not qualify for ADLT status.

Comment: Many commenters did not agree with our proposal to exclude protein-only tests under criterion A of the definition of an ADLT. The commenters stated that our proposal would exclude tests that are solely comprised of proteins from being considered an ADLT, despite statutory language that explicitly includes protein biomarker analysis under criterion A. The commenters contend that protein-only diagnostics are being used to impact patient care today, and there is no reason why complex protein-only tests should not be eligible to be considered ADLTs. For example, one commenter stated that multi-analyte protein-based tests are valuable drivers of innovation in the field of precision medicine and in many cases, provide information about a patient's disease state that is more detailed and/or advanced than what may be drawn from DNA- or RNA-based tests. Another commenter explained that a great deal of innovation is occurring with multi-analyte protein-based assays with algorithmic analyses, for instance, assays for lung nodule cancer determination, autism diagnosis, and prostate cancer metastasis risk. The same commenter stated that our proposed policy is based on a misinterpretation of the statutory language and would block innovators from using an important pathway to bring these clinically impactful assays to market. Commenters also noted that the Advisory Panel on CDLTs unanimously recommended that we revise our proposal to reflect the statutory language and include protein-only tests in the definition of an ADLT. Therefore, the commenters strongly urged us to revise criterion A of the proposed definition of an ADLT to permit tests that are solely comprised of proteins to be eligible for ADLT status.

Response: We agree that complex protein-only tests may provide information about a patient's disease state that is more comprehensive and/or advanced than what may be obtained from DNA- or RNA-based tests, and valuable innovation is occurring within multi-analyte protein-based assays, which would be consistent with our view that ADLTs are innovative tests that are new and different from any prior test already on the market. Therefore, we agree that protein-only tests should be eligible for ADLT status under criterion A. Because ADLTs are advanced tests that are apt to be complex, however, we would expect only complex protein-only tests to qualify for ADLT status as discussed further below. Therefore, we are revising criterion A of the definition of an ADLT to include tests that are solely comprised of proteins.

In addition, we are not finalizing our proposal under criterion A that a test must be a molecular pathology analysis of multiple biomarkers of DNA or RNA. In the proposed rule (80 FR 59397 through 59398) we stated that tests that analyze nucleic acids (DNA or RNA) are molecular pathology analyses, and we therefore proposed that, under criterion A, a test must be a molecular pathology analysis of RNA or DNA. Because we are now including protein-only tests under criterion A, and protein-only tests are not molecular pathology tests, we are removing the requirement that an ADLT must be a molecular pathology test. The definition of ADLT in § 414.502(1)(i) is revised to state that it is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins.

Comment: Many commenters objected to our proposed definition of a "unique algorithm," asserting that the statute requires the algorithm to be unique but not the result it produces. The commenters contend that the concept of "unique" only applies to the algorithm itself and not to the patient-specific result. Additionally, one commenter asserted that the statutory reference to a unique algorithm means that one ADLT must be different from other ADLTs. The same commenter stated that if a test comprises multiple biomarkers of DNA, RNA or proteins, incorporates an algorithm to provide a patient-specific result, and was developed by a single laboratory, there should be a presumption that the test comprises a unique algorithm because the test is the product of the development activities of the single laboratory. Another commenter stated that the statutory term "single patient-specific result" is sufficiently clear and does not require further interpretation, and that it would be unwise for us to be overly prescriptive in defining ADLT because it may prevent qualified tests from being considered ADLTs. Many commenters also mentioned that the Advisory Panel on CDLTs recommended that the definition of unique algorithm reflect the text of the statute. Therefore, the commenters recommended that we revise the definition of ADLT with respect to the unique algorithm to reflect the exact statutory language under criterion A.

Response: We considered the commenters' suggestion to use only the exact statutory language and not define unique algorithm as we proposed to do. However, we do not agree with this approach for the following reasons. First, using only the exact language of the statute would leave the public without any specific guidance on how to interpret "unique algorithm to yield a single, patient-specific result," and would leave us with no criteria by which to evaluate whether a test meets that requirement. Second, without such criteria, the requirement that a test have a "unique algorithm to yield a single, patient-specific result" would be, to some extent, self-determined by each laboratory requesting ADLT status. Without specific guidance, the laboratory seeking ADLT status would interpret the requirements under criterion A in whatever manner it chose, which could potentially vary depending on the test, and which could also vary from other laboratory interpretations. Third, if not further defined, the criterion could apply very broadly to nearly any test on the CLFS that is only done by one laboratory, which would be inconsistent with our view that ADLTs are innovative tests that are new and different from any test already on the market. Therefore, we believe it is necessary for us to interpret what it means for a unique algorithm to yield a single, patient-specific result, and to use that interpretation in establishing the requirements a test must meet to qualify as an ADLT. Additionally, as noted previously in this section, we are revising criterion A of the definition of an ADLT to include protein-only tests. However, we continue to have concerns about granting ADLT status for protein-only tests that are not advanced tests. To that end, we believe our proposed application of the unique algorithm requirement ensures that simple protein analyses would not be considered advanced tests as they are not likely to produce a patient-specific result that cannot be provided by any other test.

For the reasons discussed previously in this section, we are finalizing our proposal for the unique algorithm, and will reflect it in the definition of ADLT under criterion A as proposed.

Comment: One stakeholder urged us to remove the requirement that the test must provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests. It contends that this requirement may limit competition among tests in the marketplace and allow an inferior test to monopolize the marketplace due only to its first-comer advantage.

Response: As noted previously, our view is that ADLTs are innovative tests that are new and different from any test already on the market, which is, in part, how we interpret the requirement that the test uses a unique algorithm. We indicated in the proposed rule (80 FR 59398) that our proposed requirements for criterion A, including that the test must provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests, derive from our view of ADLTs. We do not believe the requirement, that the test must provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests, will limit competition among tests and enable the test that is developed first to dominate the marketplace. For a new test(s) that is covered under Medicare Part B and that improves upon an ADLT, if that later test does not qualify as an ADLT, it would nonetheless be paid as a CDLT based on the median private payor rate methodology, as would the ADLT after the new ADLT initial period.

Comment: One commenter stated that Congress did not intend for information that results from the test to be new and otherwise unobtainable from any other test(s). The commenter believes this additional criterion is more suitable for a coverage determination than for a determination of whether a test qualifies as an ADLT.

Response: A Medicare coverage analysis for a given CDLT is a separate, independent process from the determination of ADLT status. Whereas a coverage analysis would evaluate whether a laboratory test is reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category), the ADLT application process will determine whether a test qualifies for special temporary payment status under the CLFS. Section 1834A(d)(5)(A) of the Act requires a test to yield a single patient-specific result. The requirement we are finalizing—that the test must provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests—is the means by which we are implementing that statutory requirement. The policy is consistent with our overall view of ADLTs, and we believe it is appropriate and consistent with the statute.

Comment: One commenter stated that it appears an FDA-cleared or approved CDLT would qualify as an ADLT only if it was also offered and furnished by a single laboratory and not sold for use by a laboratory other than the laboratory that designed the test, or a successor owner of that laboratory. If that is the case, then FDA-cleared or approved tests that are designed, marketed, and distributed by manufacturers to multiple labs for "off-the-shelf" (for example, unmodified) use would not qualify as ADLTs. The commenter requested clarification in the final rule as to whether this interpretation is correct.

Response: The commenter is correct. In order to qualify for ADLT status, a test that is cleared or approved by the FDA must also be offered and furnished by a single laboratory and not sold for use by a laboratory other than the original developing laboratory or a successor owner. As discussed previously in this section, the definition of an ADLT consists of two parts. All tests must meet the first part of the definition which, as we note above, requires the test to be offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory or a successor owner. All tests must also meet the second part of the definition, but the second part presents three alternative criteria, only one of which must be met (note, we are not implementing the third criterion, C, in this final rule). If a test is FDA-cleared or approved, but sold to multiple labs as a kit for "off-the-shelf" use, then the test is offered and furnished by more than a single laboratory and would not qualify for ADLT status.

Comment: One commenter recommended that we retain flexibility outside of the annual rulemaking process to implement criterion C of the definition of an ADLT. Specifically, the commenter urged us to consider allowing MACs to apply criterion C using criteria developed by CMS that would utilize the MACs' assessment of clinical, technological, and resource similarities to other tests that have already attained ADLT status. Another commenter urged CMS to create a simple process under criterion C to allow laboratories to apply for ADLT status for tests that do not meet criterion (A) or (B).

Response: We appreciate the suggestions for how we might establish additional criteria for determining ADLT status. As discussed previously in this section, we did not propose to exercise our authority to establish other criteria by which to determine ADLT status under criterion C of section 1834A(d)(5)(C) of the Act. If we decide in the future to exercise that authority, we would propose any additional criteria through notice and comment rulemaking so the public would have an opportunity to comment.

Comment: One commenter agreed with our proposal to define a new ADLT as an ADLT for which payment has not been made under the CLFS prior to January 1, 2017.

Response: As we discussed in the proposed rule, we interpreted two sections of the statute together to determine that new ADLTs would be ADLTs for which payment has not been made under the CLFS prior to January 1, 2017. Section 1834A(d)(1)(A) of the Act requires special payment for ADLTs for which payment has not been made under the CLFS prior to April 1, 2014 (the enactment date of PAMA). Section 1834A(i) of the Act provides that, between April 1, 2014 and December 31, 2016, we must price ADLTs using the methodologies in effect on March 31, 2014. Because the statute specifies the payment methodology for new ADLTs, which is not the methodologies in place as of April 1, 2014 (crosswalking and gapfilling), we reasoned that new ADLTs would be those tests first paid on the CLFS after December 31, 2016.

The proposed definition of new ADLT correlated to the proposed implementation date of the private payor rate-based CLFS, January 1, 2017. However, as we discuss in this final rule, in response to comments, we are moving the implementation date of the private payor rate-based CLFS to January 1, 2018. We believe it is also appropriate to adopt a corresponding change for new ADLTs because the statute requires new ADLTs to be paid based on private payor rates after the new ADLT initial period. If we were to retain the proposed implementation date for new ADLTs, it could result in a new ADLT receiving payment based on the median private payor rate before January 1, 2018. For example, if the initial period for a new ADLT were to end on September 30, 2017, payment would then be based on the weighted median private payor rate beginning October 1, 2017, which would be prior to the January 1, 2018 implementation schedule for the new private payor rate-based CLFS. Therefore, the January 1, 2018 implementation date will apply to CDLTs (that are not ADLTs), as well as new ADLTs. In conjunction with this change, the payment amount for existing ADLTs will be determined based on crosswalking and gapfilling for ADLTs furnished through December 31, 2017, instead of December 31, 2016.

We are revising the definition of new ADLT in § 414.502 to reflect that a new ADLT is an ADLT for which payment has not been made under the CLFS prior to January 1, 2018. We are also making a conforming revision to § 414.507(h) to indicate that the payment amount for ADLTs that are furnished between April 1, 2014, and December 31, 2017, is based on the crosswalking or gapfilling methods described in § 414.508(a).

Comment: A few commenters urged us to clarify the process for laboratories to pursue an ADLT designation. The commenters stated that the statutory definition of ADLT is straightforward and the application process should be equally straightforward to minimize the administrative burden. One commenter recommended that any application process by which laboratories would apply for ADLT status should consist of an objective checklist of the statutory criteria, and be submitted by ADLT applicants and reviewed by CMS on a quarterly basis.

Response: As discussed in the proposed rule, we plan to establish an application process for laboratories requesting ADLT status after publication of the CLFS final rule. The information laboratories will need to provide in their application will be consistent with the definition of ADLT in § 414.502. For example, we will provide instructions for how an ADLT applicant will need to demonstrate that the test is offered and furnished by a single laboratory and has not been sold for use by a laboratory other than the laboratory that designed the test, or a successor owner of that laboratory. We will also specify the information applicants must submit to demonstrate how the test meets the requirements of criterion A or criterion B. Additionally, we will specify the timeframes by which ADLT applications will be reviewed by us, how and when applicants will be notified of our decision, and the process by which an ADLT would receive a unique HCPCS code. We appreciate commenters' input that ADLT applications should be submitted and reviewed by us on a quarterly basis, and we will take that into consideration as we establish the schedule for requesting and approving ADLT status for a laboratory test. All of this detail will be provided through subregulatory guidance after the final rule is published.

Comment: Several commenters believe that Congress did not intend for a laboratory's confidential information to have to be provided to us for the agency to be able to determine whether a test meets the definition of an ADLT. They pointed to the statute, which did not confer explicit protection from disclosure under the Freedom of Information Act (FOIA) to ADLT information submitted to us, as it did in section 1834A(a)(11) of the Act for applicable information. Therefore, the commenters urged us to only require the submission of publicly available information that would describe the algorithm and assay, but would not require applicants to submit proprietary information about the algorithm and assay. Alternatively, the commenters requested that any proprietary information required by us, or included voluntarily by the ADLT applicant in its ADLT application, be automatically protected from public disclosure under 5 U.S.C. 552(b)(4) as a trade secret.

Response: As discussed in the proposed rule (80 FR 59398 through 59399), the statute provides for the confidentiality only of applicable information disclosed by a laboratory under section 1834A(a) of the Act. The confidentiality of information provision, section 1834A(a)(10) of the Act, does not apply to section 1834A(d) of the Act, which relates to the requirements a test must meet to be an ADLT. We explained, however, that information in an ADLT application might be protected from public disclosure, even though it is not explicitly protected from disclosure under the confidentiality provisions of the statute.

Specifically, we indicated that, although the statute does not explicitly protect ADLT application information from release under FOIA (as it does under section 1834A(a)(11) of the Act for applicable information), FOIA does include an exemption for trade secrets and commercial and financial information obtained from a person that is privileged or confidential. While we do not have the authority to provide automatic protection from public disclosure under this FOIA exemption, (b)(4), if an applicant submits an ADLT application that includes trade secrets or certain commercial or financial information, specified above, it is possible the information could be withheld from public disclosure under FOIA exemption (b)(4). An applicant that wishes to protect the information submitted in an ADLT application would mark it proprietary and confidential, and substantiate that statement by expressly claiming substantial competitive harm if the information is disclosed, and demonstrating such in a separate statement by explaining how the release would cause substantial competitive harm pursuant to the process in E.O. 12600 for evaluation by us. Because there is no guarantee such information will be withheld, however, laboratories will have to decide for themselves whether to apply for ADLT status and risk the possibility of public disclosure of information they do not want to be publicly disclosed. However, we note that we would only be requiring information relevant to determining whether a test qualifies as an ADLT. Please see additional comments and responses related to confidentiality and public release of data in section II.F. of this final rule.

D. Data Collection and Data Reporting

1. Definitions

Section 1834A(a) of the Act requires applicable laboratories to report applicable information. The information is gathered or collected during a "data collection period" and then reported to the Secretary during a "data reporting period." Under the statute, the Secretary is to specify the period of time for the data collection period and the timeframe for the data reporting period. In this section, we proposed to define the terms "data collection period" and "data reporting period." In determining what the proposed data collection and data reporting periods should be, we considered our objectives to: (1) Provide applicable laboratories sufficient notice of their obligation to collect and report applicable information to CMS; (2) allow applicable laboratories enough time to collect and report applicable information; (3) give CMS enough time to process applicable information to determine a CLFS payment rate for each laboratory test; and (4) publish new CLFS payment rates at least 60 days in advance of January 1 so laboratories will have sufficient time to review the data used to calculate CLFS payment rates and prepare for implementation of the new CLFS rates on January 1.

Section 1834A(a)(4) of the Act defines the term "data collection period" as a period of time, such as a previous 12-month period, specified by the Secretary. We believed the data collection period should be a full calendar year, for example, January 1 through December 31, because a full calendar year of applicable information would provide a comprehensive set of data for calculating CLFS rates. In addition, we chose to define a data collection period as a calendar year as opposed to, for example, a federal fiscal year (October through September), so the data collection period would coordinate with the timing of the CLFS payment schedule, wherein updated CLFS payment rates are in effect on January 1 of each year. We also believed the data collection period should immediately precede the data reporting period, which is the time period during which applicable laboratories must report applicable information to us. For example, the data reporting period for the 2018 data collection period (January 1, 2018, through December 31, 2018) would begin on January 1, 2019. We believed that having the data collection period immediately precede the data reporting period would result in more accurate reporting by laboratories and, thus, more accurate rate setting by us, because laboratories would have more recent experience, and therefore, be more familiar with the information they are reporting. Further, we believed that starting the data reporting period immediately after the data collection period would limit the lag time between reporting applicable information and the use of that applicable information to determine Medicare CLFS payments, thus ensuring that we are using the most recent data available to set CLFS payment rates. For these reasons, we proposed to codify in § 414.502 that the data collection period is the calendar year during which an applicable laboratory collects applicable information and that immediately precedes the data reporting period.

We proposed a different timeline for the 2015 data collection period, which would have begun July 1, 2015, and ended December 31, 2015. While our preference would have been for the data collection period to be a full calendar year, as we proposed for subsequent data collection periods, and for it to begin after publication of proposed and final rules implementing section 1834A of the Act, we believed the statute contemplated the possibility that the first data collection period would begin prior to publication of regulations establishing the parameters for data collection. Given that the statute, which was enacted on April 1, 2014, required us to establish the parameters for data collection through rulemaking by June 30, 2015, the first data collection period that would allow for reporting in 2016 and implementation of the new payment system on January 1, 2017, would have to have been in 2015. As the statute indicates that a data collection period could be a 12-month period, and data collection requirement regulations did not have to be complete until June 30, 2015, we believed the statute anticipated that the first data collection period would begin prior to publication of the June 30, 2015 regulations, that is, 6 months prior to a final regulation. In addition, section 1834A(a)(4) of the Act does not require the data collection period to be a 12-month period, but rather, suggests that it could be, and provides us the authority to determine the length of the period. Therefore, although we could have chosen to make the 2015 data collection period a full calendar year, given that laboratories would not have notice of the data collection period until our regulations were proposed and finalized, we believed it was reasonable to limit the time period of the first data collection period to 6 months, which would have been consistent with the length of time the data collection period would have been in effect prior to a final rule if we had adopted a full calendar year data collection period in 2015 and published regulations specifying that to be the case on June 30, 2015. While we believed a full calendar year of data would be the most robust and comprehensive for setting CLFS payment rates, we stated in the proposed rule that we believed the 6-month data collection period in 2015 would still provide sufficient, reliable data with which to set rates that accurately reflect private payor rates. Therefore, we proposed to include in the definition of data collection period in § 414.502 that the data collection period for 2015 would be July 1, 2015 through December 31, 2015.

Under section 1834A(a)(1) of the Act, beginning January 1, 2016, and every 3 years thereafter (or annually in the case of an ADLT), each applicable laboratory must report applicable information to the Secretary at a time specified by the Secretary. We believed applicable laboratories should have 3 months during which to submit applicable information from the corresponding data collection period, that is, the calendar year immediately preceding the data reporting period. For example, for purposes of calculating CY 2017 CLFS rates, the data collection period would have begun on July 1, 2015, and ended on December 31, 2015, and the data reporting period would have been January 1, 2016 through March 31, 2016. We believed a 3-month data reporting period would be a sufficient amount of time for applicable laboratories to report applicable information to us. As we explained in the proposed rule, it would give us adequate time to calculate CLFS payment amounts, upload the CLFS rates on Medicare's claims processing systems, and make that data publicly available (preliminarily in September and then a final version in November) before the CLFS rates would go into effect on the following January 1. Given the magnitude of the potential changes in CLFS payment rates, to give the industry sufficient time to prepare for the next year's fee schedule, we believed final CLFS rates for the following year should be published at least 60 days prior to the beginning of the next calendar year, or no later than November 1. For these reasons, we proposed that the definition of "data reporting period" in § 414.502 be the 3-month period during which an applicable laboratory reports applicable information to CMS and that immediately follows the data collection period.

Table 1 illustrates the proposed data collection period, data reporting period, and CLFS rate year for which the data would have been used for CDLTs.

TABLE 1—PROPOSED DATA COLLECTION AND REPORTING PERIODS FOR CDLTS

Data collection period	Data reporting period	Used for CLFS rate years
7/1/2015–12/31/2015	1/1/2016–3/31/2016	2017–2019.
1/1/2018–12/31/2018	1/1/2019–3/31/2019	2020–2022.
Continues every 3rd subsequent calendar year	Continues every 3rd subsequent calendar year.	New CLFS rate every 3rd year for 3 years.

As indicated in this section, we proposed that applicable information must be reported annually for ADLTs and follow the above proposed data collection schedule on an annual basis after the first data collection period, which would be for the first and second quarters of the new ADLT initial period, and reported to us by the end of the second quarter of the new ADLT initial period (described in more detail later in this section).

2. General Data Collection and Data Reporting Requirements

Section 1834A(a)(1) of the Act requires applicable laboratories, beginning January 1, 2016, to report applicable information on CDLTs that are not ADLTs every 3 years, and every year for ADLTs, at a time specified by the Secretary. As we discussed previously, we proposed that the data collection period during which applicable laboratories collect applicable information would be the calendar year immediately prior to the data reporting period. Thus, the data reporting period is a 3-month period that would occur each year for ADLTs, from January 1 through March 31, and every third year, from January 1 through March 31, for all other CDLTs (for example, 2016, 2019, 2022, etc.). We proposed to establish these data reporting requirements in § 414.504(a).

Section 1834A(a)(3)(A) of the Act requires applicable information to be the rate paid by each private payor for the test and the associated volume of such tests for each such payor during the data collection period. In addition, section 1834A(a)(6) of the Act specifies that, in the case where an applicable laboratory has more than one payment rate for the same payor for the same test or more than one payment rate for different payors for the same test, the applicable laboratory must report each such payment rate and the volume for the test at each such rate. Furthermore, section 1834A(a)(6) of the Act provides that, beginning January 1, 2019, the Secretary may establish rules to aggregate reporting, that is, permit applicable laboratories to combine the prices and volumes for individual tests. We explained that we understand this to mean that, absent rules set by the Secretary (in 2019 or later), applicable laboratories may not aggregate data by laboratory test in reporting applicable information. Taken together, these provisions indicated to us that an applicable laboratory must report applicable information for every test it performs for each private payor, including both the amounts paid and volume. This means, should a rate for a private payor change during the data collection period, an applicable laboratory would report both the old and new rates and the volume of tests associated with each rate. We realized the amount of applicable information could be voluminous for those applicable laboratories that offer a large number of tests. However, we believed the statute requires comprehensive reporting of applicable information so the Medicare CLFS rates accurately reflect the rates paid by private payors to laboratories. Our proposed definition of applicable information in § 414.502 states that applicable information, with respect to each CDLT for a data collection period, includes each private payor rate and the associated volume of tests performed corresponding to each private payor rate, so our proposed requirement at § 414.504(a) covers the requirement for applicable laboratories to report the private payor rate for every laboratory test it performs, and to account for the volume of tests furnished at each rate. We explained that this requirement means an applicable laboratory that has more than one payment rate for the same payor for the same test, or more than one payment rate for different payors for the same test, must report each such payment rate and the volume for the test at each such rate.

To minimize the reporting burden on applicable laboratories and to avoid collecting personally identifiable information, we proposed that we would only require applicable laboratories to report the minimum information necessary to enable us to set CLFS payment rates. We indicated that we would specify the form and manner for reporting applicable information in guidance prior to the first data reporting period, but generally, in reporting applicable information, we would expect laboratories to report the specific HCPCS code associated with each laboratory test, the private payor rate or rates associated with the HCPCS code, and the volume of laboratory tests performed by the laboratory at each private payor rate. We would not permit applicable laboratories to report individual claims because claims include more information than we need to set payment rates and they contain personally identifiable information. We also would not permit applicable laboratories to report private payor names because section 1834A(a)(11) of the Act prohibits a payor from being identified on information reported by the applicable laboratory. Our guidance would reflect these instructions. Accordingly, we proposed to include in our data reporting requirements at § 414.504(b), that applicable information must be reported in the form and manner specified by CMS.

3. Data Reporting Requirements for New ADLTs

Section 1834A(d)(1)(A) of the Act requires the payment amount for new ADLTs to be based on actual list charge for an “initial period” of 3 quarters, but does not specify when this initial period of 3 quarters begins. We believed the initial period should start and end on the basis of a calendar quarter, so that the first day of the initial period would be the first day of a calendar quarter, and the last day of the initial period would be the last day of a calendar quarter (for example, January 1 and March 31, April 1 and June 30, July 1 and September 30, or October 1 and December 31). We proposed this policy to be consistent with how applicable information would be reported for CDLTs (on the basis of a calendar year, that is, 4 quarters of applicable information) and how CLFS payment rates would be updated (also on the basis of a calendar year). We explained in the proposed rule that this consistency is important so that after the new ADLT initial period is over, all CLFS payment rates (for CDLTs and ADLTs) would be posted publicly at the same time. Further, CMS updates all of its payment systems on the basis of a calendar quarter, and we believed consistency with all other CMS data systems would facilitate implementation and updates to the CLFS. Beginning and ending the new ADLT initial period on the basis of a calendar quarter would also be consistent with average sales price reporting for Medicare Part B drugs under section 1847A of the Act and desirable for the reasons stated above. If we were to start the initial period during a calendar quarter, then the end of the Q2 (the time by which applicable laboratories must report applicable information for new ADLTs) would also occur during a calendar quarter, which would mean applicable laboratories would be reporting applicable information for new ADLTs during a calendar quarter. Further, if an initial period of 3 quarters ended during a calendar quarter, we would have to begin paying for the ADLT using the methodology under section 1834A(b) of the Act during a calendar quarter. For these reasons, we proposed to start the initial period on the first day of the first full calendar quarter following the first day on which a new ADLT is performed. We proposed to refer to the initial period for new ADLTs as the "new ADLT initial period," and to codify the definition in § 414.502.

Section 1834A(d)(2) of the Act requires applicable laboratories to report applicable information for new ADLTs not later than the last day of the Q2 of the initial period. The applicable information will be used to determine the CLFS payment amount (using the weighted median methodology; see our discussion of the proposed CDLT payment methodology at 80 FR 59404 through 59406) for a new ADLT after the new ADLT initial period. We proposed to codify the reporting requirement for new ADLTs in § 414.504(a)(3).

We provided the following as an example of the proposed reporting and payment schedule for a new ADLT: A new ADLT that is first performed by an applicable laboratory during the Q1 of 2017 (for example, February 4, 2017) would start its initial period on the first day of the Q2 of 2017 (April 1, 2017). The new ADLT initial period would last for 3 full quarters, until the end of the Q4 of 2017 (December 31, 2017). The applicable laboratory would be required to report applicable information for the new ADLT by the end of the Q2 of the new ADLT initial period, which would be, in this example, the end of the Q3 of 2017 (September 30, 2017). These data would be used to calculate the payment amount for the new ADLT, which would be applied after the end of the new ADLT initial period, or starting Q1 2018 (January 1, 2018). This payment amount would last through the remainder of CY 2018. The new ADLT would then follow the annual reporting schedule for existing ADLTs, that is, CY 2017 applicable information would be reported between January 1, 2018 through March 31, 2018, and the applicable information would then be used to establish the payment amount for the ADLT that takes effect on January 1, 2019.

Table 2 illustrates the proposed data collection and reporting periods for a new ADLT using the above example.

TABLE 2—PROPOSED DATA COLLECTION AND REPORTING PERIODS FOR NEW ADLTS

ADLT first performed	Initial period	Data collection period	Data reporting period	Used for CLFS rate year
02/04/2017	04/01/2017–12/31/2017	04/01/2017–09/30/2017	By 09/30/2017	2018–2019.
		01/01/2018–12/31/2018	01/01/2019–03/31/2019	2020.

A summary of the comments we received on the proposals for data collection and reporting and our responses are discussed below.

Comment: Many commenters urged us to move the implementation date of the private payor-based rates for the CLFS to January 1, 2018. The commenters stated that a January 1, 2017 implementation date does not allow sufficient time following release of a final rule for laboratories to build their information systems to collect, assess, and report the required data. The commenters contended that insufficient lead time could result in inaccurate reporting and increase their risk of being sanctioned with civil monetary penalties. Another commenter stated that the proposed implementation schedule does not provide an adequate amount of time for us to thoughtfully consider recommendations by stakeholders and, if necessary, develop modifications to the rule. The same commenter stated that laboratories subject to reporting may not have adequate time to prepare for reporting, especially in the absence of the regulatory guidance that we would release at a later date.

The commenters suggested that a January 1, 2018 implementation date would provide applicable laboratories sufficient notice of their obligation to collect and report applicable information and adequate time to collect and report the information to us. They asserted that moving the implementation date out by 1 year would also allow us enough time to process the private payor data and calculate and publish the new CLFS rates at least 60 days prior to implementation. In addition, many commenters stated that the recommendation to move the implementation date of the new system to January 1, 2018 is consistent with PAMA, which required us to publish a final rule by June 30, 2015 to enable new rates to be in effect on January 1, 2017, thereby contemplating an 18-month period from the date of the final rule to the implementation of the new rates.

Response: We recognize that entities will need sufficient time after the publication of the final rule to build the information systems necessary to collect private payor rates, and review and verify the data collected to ensure their accuracy. We understand that a moving the implementation date to January 1, 2018 would allow for those activities as well as independent validation testing of our system to which reporting entities will report applicable information and could also provide laboratories time to perform end user testing prior to the data reporting period. A January 1, 2018 implementation date would also allow laboratories to complete the registration processes for submitting applicable information well ahead of the data reporting period. We also appreciate that stakeholders are particularly concerned about having sufficient time to prepare for the new CLFS in light of the potential for civil monetary penalties. For all of these reasons, we agree with the commenters that we should move the implementation date of the new CLFS. As the majority of commenters indicated a January 1, 2018 implementation date would be sufficient, we are moving the implementation date of the new CLFS to January 1, 2018. We are revising the data reporting schedule accordingly at § 414.504(a)(1) and (2) to require that, for CDLTs and ADLTs that are not new ADLTs, the data reporting period is a three-month period that occurs every 3 years beginning January 1, 2017.

Comment: We received comments from stakeholders requesting a January 1, 2019 implementation date for the revised CLFS. The commenters stated that moving the implementation date to January 1, 2019 would allow us enough time to finalize the rule and related guidance and for community laboratories to build systems and processes as necessary for compliance. The commenters recommended that the initial data collection period should be the first 6 months of 2017 (January 1, 2017 through June 30, 2017) and the initial data reporting period should be January 1, 2018 through March 31, 2018, with private payor-based rates effective on January 1, 2019. The commenters urged us to recognize the immense challenges many laboratories, particularly small and mid-size community laboratories, will face in implementing the new requirements while also maintaining their regular business practices of providing and billing for laboratory testing services.

Response: We considered moving the implementation date of the revised CLFS to January 1, 2019. However, based on the majority of comments we received on this issue, we are convinced that a January 1, 2018 implementation date is sufficient for laboratories to develop the necessary information systems to collect private payor rates and report applicable information. We note that, as discussed in section II.A., the low expenditure threshold will exclude laboratories that receive a relatively small amount of revenues under the CLFS from the definition of applicable laboratory. Therefore, we believe many of the community and physician office laboratories that would prefer that we implement the revised CLFS beginning January 1, 2019 will not meet the definition of applicable laboratory and will be excluded from the data reporting requirements.

Comment: Many stakeholders requested that we revise the data collection period from a full calendar year to 6 months and that we include a 6-month window between the end of the data collection period and the beginning of the data reporting period. The commenters explained that laboratories will need a minimum of 6 months to determine whether they are applicable laboratories for purposes of reporting private payor rates and if they are, to collect, format, organize, validate, and submit their data. The commenters contend that a 6-month window between the end of the data collection period and the beginning of the data reporting period will allow laboratories, which have no experience collecting and reporting private payor data to us, the necessary time to reconcile payment information with a multitude of private payors and review the accuracy of the collected data prior to submission. Commenters also recommended all data collection periods, both initial and subsequent, be 6 months instead of a full calendar year. One laboratory organization, which supported a 6-month data collection period followed by a 6-month gap before the data reporting period, commented that it performed its own analysis and found the weighted median payment amounts derived from 6 months of private payor data to be "generally consistent" with the weighted median private payor rates derived from a full year of data. Given these findings, the commenter believed we would be able to capture the data we need to calculate accurate market-based Medicare payment rates with a 6-month data collection period.

Response: We recognize that the data collection and reporting requirements in this final rule are new requirements with which the industry has no experience yet, and we understand the commenters' concerns that ample time be allotted for laboratories to review and verify the data collected before reporting it to us. We believe giving laboratories a 6-month period of time between the data collection and reporting periods will lead to higher quality data because laboratories will have the opportunity to ensure the data are complete and accurate. Additionally, as discussed in the proposed rule (80 FR 59400), although we believe a full calendar year of data would provide us with a robust and comprehensive dataset for determining CLFS payment rates, we also believe a 6-month data collection period will provide sufficient, reliable data on which to accurately set rates. Therefore, we are revising the data collection period as stakeholders suggest.

After we begin to obtain applicable information under the new private payor rate-based CLFS, we will evaluate the quality and quantity of applicable information reported in a 6-month data collection period. We will also evaluate whether a 6-month window before the reporting period continues to be necessary once the laboratory industry has more experience with the new CLFS. If we determine that a longer data collection period is necessary or appropriate, or that a 6-month period after the data collection period is no longer needed, we may propose modifications to our policies, which we would do through notice and comment rulemaking.

We are finalizing a 6-month data collection period, from January 1 through June 30, for all data collection periods, initial and subsequent. Because we are moving the implementation of the new CLFS to January 1, 2018, we no longer need to provide a shortened time frame for the initial data collection period, so we are no longer distinguishing the initial data collection period from subsequent data collection periods in the definition of data collection period in § 414.502. We are also finalizing the proposed 3-month data reporting period, from January 1 through March 31, for a data reporting period following a data collection period. This means entities will have six months between the end of the data collection period and the beginning of the data reporting period. We are revising the definition of data collection period in § 414.502 to read: Data collection period is the 6 months from January 1 through June 30 during which applicable information is collected and that precedes the data reporting period.

Table 3 illustrates the final data collection and reporting periods, as described above, and the CLFS rate year for which the data will be used for CDLTs.

TABLE 3—FINAL DATA COLLECTION AND REPORTING PERIODS FOR CDLTS

Data collection period	Six month window	Data reporting period	Used for CLFS rate years
1/1/2016–6/30/2016	7/1/2016–12/31/2016	1/1/2017–3/31/2017	2018–2020.
1/1/2019–6/30/2019	7/1/2019–12/31/2019	1/1/2020–3/31/2020	2021–2023.
Continues every 3rd subsequent calendar year.	Continues every 3rd subsequent calendar year.	Continues every 3rd subsequent calendar year.	New CLFS rate every 3rd year.

Comment: One commenter, that also urged us to implement the new CLFS on January 1, 2018, recommended that CMS implement the new ADLT payment methodology on January 1, 2017 as proposed. Additionally, the commenter stated that assignment of specific codes for ADLTs should proceed on time as intended by statute. The commenter contends that, because data collection for new ADLTs would not begin until 2017, delaying implementation of the new ADLT payment methodology is not necessary to accommodate any change we might adopt in reporting for existing ADLTs and CDLTs.

Response: As discussed in section II.A. of this final rule, the proposed definition of new ADLT correlated to the proposed implementation date of the private payor rate-based CLFS, January 1, 2017. As we discuss previously in this section, in response to comments, we are moving the implementation date of the private payor rate-based CLFS to January 1, 2018. We believe it is also appropriate to adopt a corresponding change in the implementation date for new ADLTs because the statute requires new ADLTs to be paid based on private payor rates after the new ADLT initial period. If we were to retain the proposed implementation date for new ADLTs, conceivably, they could start being paid based on the median private payor rate before the revised CLFS is implemented. For example, if a new ADLT initial period were to end on September 30, 2017, payment would be based on the weighted median private payor rate beginning October 1, 2017, which would be prior to the January 1, 2018 implementation schedule for the new private payor rate-based CLFS. Therefore, the January 1, 2018 implementation date will apply to CDLTs, including ADLTs. We are modifying the definition of a new ADLT in § 414.502 to specify that a new ADLT is an ADLT for which payment has not been made under the CLFS prior to January 1, 2018.

Comment: Several commenters urged us to revise our proposed definition of new ADLT initial period to ensure that private payor rates can be reported and used to develop market-based rates for new ADLTs after the new ADLT initial period is over. The commenters stated that using the date a test is first performed as the starting point for determining when the new ADLT initial period begins may result in insufficient private payor data being reported to us. The commenters also stated that if the new ADLT initial period were to begin prior to Medicare coverage for the test (which one commenter suggested could take 6 to 12 months or longer), the time during which the new ADLT can be paid the actual list charge rate could expire before Medicare pays at that rate, which the commenters contended would defeat the purpose of the statutory provision creating a specific payment scheme for new ADLTs.

Some commenters suggested the new ADLT initial period should only begin once Medicare coverage is available for that particular test. Other commenters suggested that the CMS approval date for ADLT status should trigger the start date for the new ADLT initial period. For example, if a test is first performed on February 4, 2017, and CMS does not confer ADLT status until March 14, 2018, then it would be March 14, 2018, and not February 4, 2017, that would trigger the start of the new ADLT initial period.

Other commenters pointed out that CMS's proposed approach requires, before an ADLT can be paid at the actual list charge rate, that the laboratory has first sought and been granted ADLT status for its laboratory test and that Medicare coverage in the form of an initial claim determination or a local coverage policy has occurred. As such, some commenters believed we should clarify our proposed policy, while others suggested we should adopt a new policy, that when the agency says the initial period starts on the first day of the next calendar quarter following the first day on which the new ADLT is performed, that means the agency has already deemed the test to be an ADLT and Medicare coverage has been established.

Response: As discussed in the proposed rule (80 FR 59401), we proposed to start the new ADLT initial period on the first day of the first full calendar quarter following the first day on which a new ADLT is performed. We agree with commenters that our policy should try to ensure that a new ADLT is paid actual list charge during the new ADLT initial period.

We recognize that our proposed policy to tie the start of the new ADLT initial period to the date the test is first performed could mean new ADLTs will not be paid actual list charge. We understand that a Medicare coverage determination could be a lengthy process for the types of tests that are likely to qualify as ADLTs and that, consequently, a test may be available on the market and paid by private payors before Medicare covers and pays for it. Under our proposed policy, if the test has been available to private payors long before we grant ADLT status and provide Medicare coverage, the new ADLT initial period may have expired and the actual list charge rate would no longer apply.

We believe making the start of the new ADLT initial period contingent upon us making a Medicare Part B coverage determination for the test and approving the test for ADLT status will address stakeholder concerns that the new ADLT initial period might expire before Medicare makes payment at the actual list charge. We are revising our proposal accordingly. The new ADLT initial period will begin only when the test has been both covered under Medicare Part B and approved for ADLT status, regardless of the order in which the events take place. To ensure that both events have occurred, the date that triggers the date on which the new ADLT initial period begins will be the later of the two.

For example, if we approve a single laboratory's request for ADLT status on March 4, 2018, and a coverage determination for that test is made on August 10, 2018, the date that triggers the new ADLT initial period is August 10, 2018. The new ADLT initial period would begin October 1, 2018 because that is the first day of the first full calendar quarter following August 10, 2018. In another example, if a coverage determination for the test is made on April 6, 2018, and we approve a single laboratory's request for ADLT status on May 1, 2018, the date that triggers the new ADLT initial period would be May 1, 2018. The new ADLT initial period would begin July 1, 2018 because that is the first day of the first full calendar quarter following May 1, 2018.

To reflect this change to the start date of a new ADLT initial period, we are revising the definition of new ADLT initial period in § 414.502 to mean a period of 3 calendar quarters that begins on the first day of the first full calendar quarter following the later of the date a Medicare Part B coverage determination is made or ADLT status is granted by us. In light of this change, we are also revising the data reporting requirements in § 414.504(c) to no longer require a laboratory seeking new ADLT status for its test to attest to the date the new ADLT is first performed as this information is no longer relevant for determining the start date of the new ADLT initial period.

Additionally we clarify here that the start date of a new ADLT initial period is separate and distinct from the date that corresponds to the definition of the actual list charge. As discussed in this final rule, the actual list charge is the publicly available rate on the first day the new ADLT is obtainable by a patient who is covered by private insurance, or marketed to the public as a laboratory test a patient can receive even if the test has not yet been furnished on that date. Therefore, the actual list charge amount could be known well before the start of the new ADLT initial period. For more discussion of the actual list charge, please refer to section II.H. in this final rule.

We also recognize that if private payors do not cover and pay for a test until after the second quarter of the new ADLT initial period, no private payor data may be reported for the test. In that case, we would use crosswalking and gapfilling methodologies to determine pricing for the new ADLT after the new ADLT initial period. We note that the use of crosswalking and gapfilling for determining pricing for ADLTs in such circumstances is consistent with how we will price other CDLTs for which no applicable information is reported in a data reporting period. We believe the requirement for laboratories to collect and report private payor rate data annually for ADLTs would mitigate most concerns about prolonged reliance on crosswalking and gapfilling to price ADLTs rather than private payor rates. We note that under the recoupment of payment for new ADLTs if actual list charge exceeds the market rate provision (section 1834A(d)(4) of the Act), the weighted median private payor rate determined during the new ADLT initial period is compared to the actual list charge. If no private payor rate data is reported during the new ADLT initial period, there would be no weighted median private payor rate to compare the actual list charge to and the recoupment provision would not be applicable. For more information on the recoupment of payment for new ADLTs, please refer to section II.H in this final rule.

Table 4 illustrates the final data collection and reporting period for a new ADLT, using the example above, where a test receives a Medicare Part B coverage determination on April 6, 2018 and ADLT status is granted by CMS on May 1, 2018.

TABLE 4—EXAMPLE OF FINAL DATA COLLECTION AND REPORTING PERIOD FOR NEW ADLTS

Test is covered by medicare Part B	ADLT status is granted	New ADLT initial period (actual list charge)	Data collection period	Data reporting period	Data used for CLFS (weighted median private payor rate)
4/6/2018	5/1/2018	7/1/2018–3/31/2019	7/1/2018–12/31/2018	By 12/31/2018	4/1/2019–12/31/2020.

Table 5 illustrates the final data collection and reporting periods for new ADLTs after the new ADLT initial period, using the example above, where the new ADLT initial period ends on March 31, 2019.

TABLE 5—EXAMPLE OF FINAL DATA COLLECTION AND REPORTING PERIODS FOR NEW ADLTS

[After New ADLT Initial Period]

Data collection period	Six month window	Data reporting period	Used for CLFS rate year
1/1/2019–6/30/2019	7/1/2019–12/31/2019	1/1/2020–3/31/2020	2021.
1/1/2020–6/30/2020	7/1/2020–12/31/2020	1/1/2021–3/31/2021	2022.
Continues every year	Continues every year	Continues every year	New CLFS rate every year.

Comment: One commenter stated that, given that commercial payors' processes to price new codes and tests is lengthy, three quarters is not adequate time for a sufficient number of insurers to have paid for the test and contributed to the private payor data on which we will price the test. To address this concern, the commenter recommended that we extend the new ADLT initial period to one calendar year before reporting is required.

Response: Section 1834A(d)(1) of the Act requires a new ADLT initial period to be 3 quarters, and section 1834A(d)(2) of the Act requires applicable information for a new ADLT to be reported no later than the last day of the second quarter of the new ADLT initial period. As the statute is explicit about those time frames, we do not believe it would permit the new ADLT initial period to be a full calendar year or the first reporting to be after the new ADLT initial period is over. As discussed in response to a previous comment, if no private payor rate data are reported by the end of the second quarter of the new ADLT initial period, we will use crosswalking and gapfilling methodologies to determine pricing for the ADLT. We believe, however, the annual data collection and reporting requirement for ADLTs should alleviate concerns about the extended use of crosswalking and gapfilling, as opposed to private payor rates, to determine payment amounts for ADLTs.

E. Data Integrity

1. Penalties for Non-Reporting

Section 1834A(a)(9)(A) of the Act authorizes the Secretary to apply a CMP if the Secretary determines that an applicable laboratory has failed to report, or has made a misrepresentation or omission in reporting, information under section 1834A(a) of the Act for a CDLT. In these cases, the Secretary may apply a CMP in an amount of up to $10,000 per day for each failure to report or each such misrepresentation or omission. Section 1834A(a)(9)(B) of the Act further provides that the provisions of section 1128A of the Act (other than sections (a) and (b)) shall apply to a CMP under this paragraph in the same manner as they apply to a CMP or proceeding under section 1128A(a) of the Act. Section 1128A of the Act governs CMPs that apply to all federal health care programs. Thus the provisions of section 1128A of the Act (specifically sections 1128A(c) through 1128A(n) of the Act) apply to a CMP under section 1834A(a)(9) of the Act in the same manner as they apply to a CMP or proceeding under section 1128A(a) of the Act. We noted that a similar provision is included in the law under section 1847A(d)(4) of the Act with regard to the reporting of average sales price by the manufacturer of a drug or biological. Given the similarity between sections 1834A(a)(9)(A) and 1847A(d)(4) of the Act, we proposed to adopt a provision in § 414.504(e) for implementing section 1834A(a)(9)(A) of the Act that is similar to § 414.806, the regulation governing drug manufacturers' reporting of Part B drug prices under section 1847A(d)(4) of the Act. Following the final publication of this rule, we anticipate issuing guidance further clarifying these requirements.

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: Several commenters commented on the proposed CMPs of up to $10,000 per day per violation and said the amount should be reconsidered, particularly for community laboratories that cannot afford such penalties. The commenters also suggested that CMS only apply penalties in cases where there is evidence that a laboratory intentionally provided inaccurate or mistaken information.

Response: The statute authorizes CMPs of up to $10,000 per day per violation. However, in situations where our review reveals that the data submitted is incomplete or incorrect, we will work with the OIG to assess whether a CMP should be applied, and if so, the appropriate amount based on the specific circumstances. Although the statute authorizes CMPs of up to $10,000 per day per violation, we recognize that this is the maximum statutory amount, and not a minimum. The actual penalty imposed will be determined based on the facts and circumstances of each violation.

We note that this amount was recently amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Public Law 114–74, November 2, 2015) (the 2015 Act), which amends the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act) (Pub. L. 101–410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C. 2461 note 2(a)). The Inflation Adjustment Act required all agencies, including HHS, to adjust any CMPs within their jurisdiction by increasing the maximum CMP or the range of minimum and maximum CMPs, as applicable, for each CMP by the cost-of-living adjustment. The 2015 Act was enacted to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. Among other things, it revises the method of calculating inflation adjustments so that, instead of the significant rounding methodology applied under the Inflation Adjustment Act, penalty amounts are now simply rounded to the nearest $1. Accordingly, in applying the requirements of the Inflation Adjustment Act, as amended, to the penalty amounts specified in section 1834A(a)(9) of the Act, the Secretary may assess CMPs of up to $10,017 per day per violation beginning on the effective date of this rule. We have revised § 414.504(e) to reflect this statutory adjustment. The 2015 Act also requires agencies to publish annual adjustments not later than January 15 of every year after publication of the initial adjustment. Therefore, subsequent to this initial adjustment, CMP adjustments applicable to section 1834A of the Act will be updated annually through regulations published by the Secretary no later than January 15 of every year.

Comment: Several commenters requested clarification as to what constitutes an error that warrants a penalty, and stated that CMS should not apply any penalties or sanctions for reporting errors until an appeals process is outlined. Some commenters stated that CMS indicated in the proposed rule that full implementation of the new CLFS regulations will take between 5 and 6 years, and suggested that no penalties be assessed during this time.

Response: As previously mentioned, following the publication of this final rule, we will issue additional guidance on the assessment of CMPs, including what would constitute a failure to report or a misrepresentation or omission in reporting. We also note that we do not intend to assess CMPs for minor errors. The actual penalty imposed will be determined based on the facts and circumstances of each violation. While full implementation of the new CLFS regulations will take several years, it is critical that reporting entities provide accurate and complete information at the outset so that accurate prices can be set, and while we do not expect that CMPs will be assessed frequently, we believe the ability to assess CMPs on reporting entities when appropriate is consistent with our statutory authority. Section 1834A(a)(9)(B) of the Act further provides that the provisions of section 1128A of the Act (other than sections (a) and (b)) shall apply to a CMP under this paragraph in the same manner as they apply to a CMP or proceeding under section 1128A(a) of the Act.

Comment: A commenter stated that the economics and other characteristics of the laboratory industry differ greatly from the pharmaceutical industry making the comparison to Part B drugs inapplicable.

Response: We agree there are important differences between the pharmaceutical industry and the laboratory industry, but believe the general approach taken for the application of CMPs for violations in reporting drug prices is an appropriate model to consider when we develop guidance on the application of CMPs for violations in reporting of applicable information.

Comment: A commenter stated that CMPs can be an effective tool for encouraging data reporting and ensuring compliance with the PAMA reporting obligations but that there will be significant confusion within the laboratory community initially. The commenter requested that CMS not impose CMPs during the initial cycle on any laboratory that has shown a good faith effort to comply with the reporting requirements, and that CMS should notify applicable laboratories of their reporting obligations to ensure compliant reporting and to reduce the likelihood of penalties.

Response: We appreciate the commenter's understanding of the important role of CMPs in ensuring accurate and complete data reporting and acknowledge the commenter's concerns regarding the provision of data during the initial reporting period. We are uncertain as to what the commenter means by "any laboratory that has shown a good faith effort to comply with the reporting requirements" As we have noted previously, we do not intend to assess CMPs for minor errors, and will provide additional information in subregulatory guidance to facilitate compliant reporting and to reduce the likelihood of penalties. Additionally, we are clarifying in § 414.504(e) that the CMPs will be assessed at the reporting entity level, not at the applicable laboratory level, to ensure consistency with the data reporting and certification requirements that the reporting entity is obligated to follow, as addressed in the other paragraphs in § 414.504.

Comment: Some commenters stated that smaller laboratories without sufficient administrative staff face challenges in reporting as compared to larger, well-resourced laboratories. These commenters suggested that the size of the penalty should correspond to the size of the laboratory, so that laboratories with limited resources would not be forced to close as a result of such penalties.

Response: We will consider all relevant information when determining the amount of a CMP, and we will work with the OIG to ensure that any penalties assessed are fairly applied. The purpose of PAMA is to collect complete and accurate data in order to set payment rates, not to force a laboratory to close as a result of a CMP assessment.

Comment: Some commenters were concerned that the period to understand and comply with the data requirements is too short and could compromise the integrity of the data submitted.

Response: In section II.D of this final rule, we discuss our final data collection and reporting process, which is changed from our proposal in the proposed rule. Under the process we are adopting in this final rule, applicable laboratories will have a 6-month data collection period, followed by a 6-month period between the end of the data collection period and the beginning of the data reporting period to allow applicable laboratories time to ensure the accuracy of their data, followed by a 3-month data reporting period during which reporting entities will report applicable information to us. We believe this process will provide applicable laboratories adequate time to understand and prepare for the submission of the required data.

Comment: Some commenters noted that accidental errors are inevitable with a new, first-of-its-kind, untested laboratory price reporting system, and the associated fines are significant. These commenters also opined that the new reporting requirements will require significant changes for the clinical laboratory community to undertake with no funding provided to make those changes, and that implementation of this law is being fast-tracked, which will lead to mistakes and unexpected problems.

Response: As discussed in section II.D.3 of this final rule, we are moving the implementation date of section 1834A of the Act to January 1, 2018. We expect applicable laboratories will have sufficient time to review their data for accuracy and completeness during the 6-month time period we are affording between the end of the data collection period and the beginning of the data reporting period. We recognize that there is a cost associated with the development and submission of data under section 1834A of the Act, but we believe this data submission process is an essential mechanism to establish fair and accurate Medicare payment rates for CDLTs. We are proceeding with implementation of the new reporting requirements in accordance with the statutory requirements, notwithstanding the new implementation date of January 1, 2018.

2. Data Certification

Section 1834A(a)(7) of the Act requires that an officer of each laboratory must certify the accuracy and completeness of the reported information required by section 1834A(a) of the Act. We proposed to implement this provision by requiring in § 414.504(d) that the President, CEO, or CFO of an applicable laboratory or an individual who has been delegated authority to sign for, and who reports directly to, the laboratory's President, CEO, or CFO, must sign a certification statement and be responsible for assuring that the applicable information provided is accurate, complete, and truthful, and meets all the reporting parameters. We stated that we would specify the processes for certification in subregulatory guidance prior to January 1, 2016.

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: A few commenters objected to our plan to specify the processes for certification in subregulatory guidance prior to January 1, 2016, stating that some of these process issues need to be resolved in the final rule before subregulatory guidance is issued. Others have asked that the subregulatory guidance be issued as soon as possible.

Response: We will issue subregulatory guidance specifying the certification process for the submission of applicable information following publication of this final rule. As discussed in section II.D.3 of this final rule, we are moving the implementation date of the revised CLFS to January 1, 2018, so we now expect to issue the subregulatory guidance prior to January 1, 2018.

Comment: Some commenters requested that CMS create a certification form for applicable laboratories that states that the information and statements submitted are accurate and complete to the best of the laboratory's knowledge and the submission is made in good faith.

Response: We appreciate the commenters' suggestion and will take it into consideration as we develop subregulatory guidance for the certification process following the publication of this final rule.

Comment: Some commenters stated that most laboratory Presidents, CEOs, and CFOs are not personally familiar with the volume and private payor rates for each laboratory test their labs offer, and they should not be required to certify the accuracy of the data submitted. The commenter suggested that a laboratory officer should be responsible for certifying that the data submitted is accurate to the best of his or her knowledge.

Response: We agree with the commenter and in accordance with the changes to the data reporting requirements in this final rule, we have revised § 414.504(d) to require the President, CEO, or CFO of the reporting entity or an individual who has been delegated authority to sign for, and who reports directly to, such an officer to certify the accuracy of the data submitted for the reporting entity.

F. Confidentiality and Public Release of Limited Data

Section 1834A(a)(10) of the Act addresses the confidentiality of the information disclosed by a laboratory under section 1834A(a) of the Act. Specifically, the paragraph provides that, notwithstanding any other provision of law, information disclosed by a laboratory under section 1834A(a) of the Act is confidential and must not be disclosed by the Secretary or a Medicare contractor in a form that discloses the identity of a specific payor or laboratory, or prices charged or payments made to any such laboratory, except as follows:

- As the Secretary determines to be necessary to carry out section 1834A of the Act;
- To permit the Comptroller General to review the information provided;
- To permit the Director of the Congressional Budget Office (CBO) to review the information provided; and
- To permit MedPAC to review the information provided.

These confidentiality provisions apply to information disclosed by a laboratory under section 1834A(a) of the Act, the paragraph that addresses reporting of applicable information for purposes of establishing CLFS rates, and we interpreted these protections as applying to the applicable information that applicable laboratories report to CMS under proposed § 414.504(a). We did not interpret section 1834A(a)(10) of the Act as applying to other information laboratories may submit to CMS that does not constitute applicable information, for example, information regarding an applicable laboratory's business structure, such as its associated NPI entities, or information submitted in connection with an application for ADLT status under section 1834A(d) of the Act, including evidence of a laboratory's empirically derived algorithms and how the test provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests.

In section II.H of this final rule, we discuss in more detail how we will use the applicable information reported under § 414.504 to set CLFS payment rates, and intend to make available to the public a list of test codes and the CLFS payment rates associated with those codes, which is the same CLFS information we currently make available. This information would not reveal the identity of a specific payor or laboratory, or prices charged or payments made to a specific laboratory (except as noted below), and thus, we believed continuing to publish this limited information would allow us to comply with section 1834A(a)(10) of the Act while continuing to provide necessary information to the public on CLFS payment amounts.

As noted above, section 1834A(a)(10) of the Act lists four instances when the prohibition on disclosing information reported by laboratories under section 1834A(a) of the Act would not apply, the first being when the Secretary determines disclosure is necessary to carry out section 1834A of the Act. We believe certain disclosures will be necessary for us to administer and enforce the new Medicare payment system for CDLTs. For example, it may be necessary to disclose to the HHS OIG confidential data needed to conduct an audit, evaluation, or investigation or to assess a CMP, or to disclose to other law enforcement entities such as the Department of Justice confidential data needed to conduct law enforcement activities. Therefore, we proposed to add those entities to the list of entities in § 414.504(f) to which we may disclose applicable information that is otherwise confidential. Additionally, there may be other circumstances that require the Secretary to disclose confidential information regarding the identity of a specific laboratory or private payor. If we determine that it is necessary to disclose confidential information for other circumstances, we would notify the public of the reasons through a **Federal Register** announcement, if deemed necessary, or via a CMS Web site prior to making such disclosure.

Also, we believed that codes and associated CLFS payment rates published for ADLTs may indirectly disclose the identity of the specific laboratories selling those tests, and, for new ADLTs, payments made to those laboratories. As explained in this section, ADLTs are offered and furnished only by a single laboratory. Thus, in the proposed rule, we believed publishing the test code and associated CLFS payment rate for an ADLT would indirectly reveal the identity of the laboratory because only a single laboratory would be offering and furnishing that test. Moreover, because Medicare will pay actual list charge for a new ADLT during the new ADLT initial period, publishing the test code and associated CLFS rate for a new ADLT would, we believe, reveal the payments made to the laboratory offering and furnishing that test. We believe section 1834A(a)(10)(A) of the Act authorizes us to publish the test codes and associated CLFS payment rates for ADLTs and we do not believe we can do so without indirectly revealing ADLT laboratory identities and payments made to those laboratories. However, because the actual list charge for a new ADLT would already be publicly available, we do not believe laboratories will be harmed by our publishing the CLFS rates for new ADLTs. We indicated that we would not publish information that directly discloses a laboratory's identity, but we could not prevent the public from associating CLFS payment information for an ADLT with the single laboratory offering and furnishing the test.

Section 1834A(a)(10) of the Act also prohibits a Medicare contractor from disclosing information under section 1834A(a) of the Act in a form that reveals the identity of a specific payor or laboratory, or prices charged or payments made to any such laboratory. We stated in the proposed rule that we did not expect this prohibition to be problematic as applicable laboratories would be reporting applicable information to CMS and not the MACs. When a MAC sets rates under our new policies, we expect the MAC will follow its current practice for pricing when developing a local payment rate for an item or service that does not have a national payment rate, that is, it would only disclose pricing information to the extent necessary to process and pay a claim.

We proposed to implement the confidentiality requirements of section 1834A(a)(10) of the Act in § 414.504(f).

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: Many commenters agreed with the confidentiality provisions outlined in the proposed rule, but expressed concern regarding disclosure of certain information laboratories would be required to report under section 1834A of the Act. For example, commenters were concerned that information such as payor names could be revealed to the public. One commenter suggested that payor names are not necessary to carry out the requirements of section 1834A, and that it is also unnecessary for the Comptroller General, Director of the Congressional Budget Office, and MedPAC to review information that will be reported by laboratories. The commenter requested that CMS ensure the rates paid by specific payors are not easy to discern.

A few commenters requested that CMS protect all reported information from public disclosure. One commenter requested assurance that disclosures made as the Secretary determines to be necessary to carry out the requirements of the law are made judiciously and without revealing more information than is truly necessary.

A commenter indicated that the form and manner specified for reporting applicable information should ensure that private payor names are not reported. Along those same lines, another commenter suggested that language be added to § 414.504(b) to explicitly state that private payor names are to be omitted from or otherwise obscured in all reporting materials. The commenter opined that including this instructive language solely in separate subregulatory guidance materials would be insufficient and that it needs to be included in the regulation to make the requirements clear, eliminate any uncertainty regarding confidentiality for clinical laboratories subject to the new law, and protect price competition in the marketplace.

Response: We appreciate the commenters' concerns and suggestions regarding the confidentiality and data reporting provisions. As discussed above, CMS and the MACs will not publicly disclose applicable information reported under section 1834A(a) of the Act in a form that would reveal the identity of a specific payor or laboratory, or prices charged or payments made to a specific laboratory. While the commenter is correct that we can fulfill our obligations under section 1834A without disclosing the information to the Comptroller General, the Director of CBO, and MedPAC, the statute specifically provides for disclosure to those entities to permit them to review the information, if needed to carry out their responsibilities. Section 1834A(a)(10)(A) of the Act also authorizes us to disclose the information as we determine necessary to implement section 1834A(a) of the Act, which we proposed to use for such activities as oversight and enforcement in conjunction with the HHS OIG or the Department of Justice. We assure commenters that we will limit disclosure of information for the purpose of conducting such activities to only what is truly necessary.

Although we appreciate the commenter's suggestion for adding language to the regulations to explicitly state that private payor identities are not to be revealed in reporting applicable information, we do not believe it is necessary. Section 1834A(a)(11) of the Act specifies that a payor shall not be identified on applicable information. In our data reporting requirements at

§ 414.504(b), we require that applicable information must be reported in the form and manner specified by us. We do not agree it is necessary to include in the regulations the specific form and manner for submitting applicable information. As we discussed in section II.D.2 of this final rule, we will only require the minimum information necessary to be reported to enable us to set CLFS payment rates. Generally, in reporting applicable information, we expect laboratories to report the specific HCPCS code associated with each laboratory test, the private payor rate or rates associated with the HCPCS code, and the volume of laboratory tests performed by the laboratory at each private payor rate. We will not permit individual claims to be reported because claims include more information than we need to set payment rates and they contain personally identifiable information. We also will not permit private payor names to be reported because section 1834A(a)(11) of the Act prohibits a payor from being identified on information reported. Our guidance will reflect these instructions.

Comment: Many commenters expressed concern that our proposal to use the existing annual update process, in which we publish only a list of test codes and the CLFS payment rates associated with those codes, would be insufficient information for the public to review the new payment rates established under section 1834A of the Act. The commenters stated, with a new reporting system of this magnitude and complexity that relies on laboratories providing correct and uniform information, it is essential for CMS to also explain how it derived the new payment rates. Rather than simply announcing payment amounts, the commenters suggested CMS allow for notice and comment rulemaking to provide an opportunity for the agency to outline what data it received, from how many laboratories and the type(s) of laboratories that submitted data (for example, physician office laboratories, independent laboratories), the variances in the data, and how CMS reconciled any variances. Commenters suggested that, for laboratories to appropriately comment on the new CLFS rates under section 1834A, they will need to be able to review more data than just the rates.

Response: In section II.H. of this final rule, we provide a comprehensive explanation of how the payment rates will be set under section 1834A of the Act, and we believe that is sufficient for the laboratory industry to understand how the rates we will announce are established.

As indicated above in this section, we intend to make available to the public a list of test codes and the CLFS payment rates (that is, the weighted median of private payor rates) associated with those codes, which is the same CLFS information we currently make available to the public annually in November. However, under the new process, we expect to release this file earlier than November so the public will have more opportunity to review and comment on the payment rates before they are implemented. In addition, to address commenters' concerns about data transparency, we also intend to make available to the public, a file that includes summary or aggregate-level private payor rate and volume data for each test code such as, the unweighted median private payor rate, the range of private payor rates, the total, median and mean volume, and the number of laboratories reporting. Such information will also be released to the public before the final rates are published to better enable the public to comment on the general accuracy of the reported data. In providing this information, we will not release any information that identifies a payor or a laboratory.

In addition to publishing the aggregate-level private payor rate and volume data, we are also exploring whether we can make available a file of the raw data, that is, the actual, un-aggregated data that is reported as applicable information for an applicable laboratory. We believe this process could provide even more transparency for the public to review and comment on the new CLFS payment rates before they are made effective. Details of this process, if we decide we can release the raw data, would be provided in subregulatory guidance.

Although we noted in the proposed rule that we cannot prevent the public from associating applicable information for an ADLT with the single laboratory offering and furnishing the test (80 FR 59402), we have given further consideration to how we may protect the identity of such laboratories from public disclosure. Although we believe we could release the applicable information for ADLTs in raw or aggregate form under the authority of section 1834A(a)(10)(A) of the Act, we recognize and appreciate that commenters are especially concerned about confidentiality and risk of disclosure of propriety information. Therefore, we have decided, for tests we consider to be uncommon or that we know to be provided only by a single laboratory (such as for new ADLTs), we will not release applicable information in aggregate form, or raw form if we decide we can release the raw data. However, we will provide the HCPCS code and CLFS rate associated with those tests consistent with our current annual publication of the CLFS file. We consider a test to be "uncommon" if it is offered or furnished by only a few laboratories or if it is paid by only a few private payors. We will clarify further what we mean by "a few laboratories" and "a few private payors" after we evaluate the private payor data we receive in the first data reporting period of January 1, 2017 through March 31, 2017, and we will publish that clarification along with the public files we discussed above in this section.

Comment: A few commenters believed proprietary algorithms that are submitted as part of an ADLT application should be protected from public disclosure. To that end, they requested we make proprietary and confidential information submitted for purposes of requesting ADLT status exempt from disclosure under the Freedom of Information Act (FOIA) Exemption 4. These commenters indicated that the proprietary information should be identified as a "trade secret" at the time of the ADLT application and thus should be protected from disclosure under FOIA.

Response: As discussed in section III.C of this final rule, we do not have the statutory authority to automatically exempt confidential information submitted as part of an ADLT application from public disclosure. The statute provides for the confidentiality of applicable information disclosed by a laboratory under section 1834A(a) of the Act, but section 1834A(d) of the Act, which relates to the requirements a test must meet to be an ADLT, does not.

FOIA includes an exemption for trade secrets and commercial and financial information obtained from a person that is privileged or confidential. While we do not have the authority to provide automatic protection from public disclosure under FOIA Exemption 4, if an applicant submits an ADLT application that includes trade secrets or certain commercial or financial information, specified above, it is possible the information could be withheld from public disclosure under the FOIA exemption. An applicant that wishes to protect the information submitted in an ADLT application would mark it proprietary and confidential, and substantiate that statement by expressly claiming substantial competitive harm if the information is disclosed, and demonstrating such in a separate statement by explaining how the release would cause substantial competitive harm pursuant to the process in E.O. 12600 for evaluation by CMS.

Comment: One commenter reasoned that the submission of evidence relating to an empirically derived algorithm is voluntary because laboratories could apply for ADLT status under criterion B by submitting validation of premarket clearance or approval from the FDA. Therefore, the commenter believes the information submitted as part of an ADLT application under criterion A is protected from public disclosure under FOIA Exemption 4 because the voluntarily provided information should be kept confidential if it is of the kind the company would not customarily release to the public.

Response: An ADLT applicant may request ADLT status for a laboratory test based on criterion A or criterion B. If an applicant chooses to submit a request for ADLT status under criterion A, the applicant will be required to submit evidence of the empirically derived algorithm and show how a test provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests. Information voluntarily submitted to the government may, in some circumstance, be protected from disclosure by FOIA in accordance with the goal of encouraging the cooperation of persons that may have information that would be useful to the government. The submission of information to support an ADLT application is not voluntary in that respect, and the protections from FOIA regarding voluntary information, as cited by the commenter, do not apply to information submitted by an applicant requesting ADLT status for a laboratory test under criterion A.

G. Coding for Certain Clinical Diagnostic Laboratory Tests (CDLTs) on the CLFS

Section 1834A(e) of the Act includes coding requirements for certain new and existing ADLTs and laboratory tests that are cleared or approved by the FDA. In this section, we describe our current coding system for the CLFS and how we proposed to utilize aspects of this system to implement the coding provisions in section 1834A(e) of the Act.

1. Background

Currently, new tests on the CLFS receive HCPCS level I codes (CPT) from the American Medical Association (AMA). The CPT is a uniform coding system consisting of descriptive terms and codes that are used primarily to identify medical services and procedures furnished by physicians, suppliers, and other health care professionals. Decisions regarding the addition, deletion, or revision of CPT codes are made by the AMA, and published and updated annually by the AMA. Level II of the HCPCS is a standardized coding system used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). Because Medicare and other insurers cover a variety of services, supplies, and equipment that are not identified by CPT codes, the HCPCS level II codes were established for submitting claims for these items.

Within CMS, the CMS HCPCS Workgroup, which is comprised of representatives of major components of CMS and consultants from pertinent Federal agencies, is responsible for all revisions, deletions, and addition to the HCPCS level II codes. As part of its deliberations, the CMS HCPCS Workgroup may develop temporary and permanent national alpha-numeric HCPCS level II codes. Permanent HCPCS level II codes are established and updated annually, whereas temporary HCPCS level II codes are established and updated on a quarterly basis. Temporary codes are useful for meeting, in a short time frame, the national program operational needs of a particular insurer that are not addressed by an already existing national code. For example, Medicare may need additional codes before the next annual HCPCS update to implement newly issued coverage policies or legislative requirements.

Temporary HCPCS level II codes do not have established expiration dates; however, a temporary code may be replaced by a CPT code, or the CMS HCPCS Workgroup may decide to replace a temporary code with a permanent HCPCS level II code. For example, a laboratory may request a code for a test in the middle of a year. Because permanent codes are assigned only once a year, the CMS HCPCS Workgroup may assign the laboratory test a temporary HCPCS level II code. The temporary code may be used indefinitely or until a permanent code is assigned to the test. Whenever the CMS HCPCS Workgroup establishes a permanent code to replace a temporary code, the temporary code is cross-referenced to the new permanent code and removed.

"G codes" are temporary HCPCS level II codes that we use to identify professional health care procedures and services, including laboratory tests, that would otherwise be identified by a CPT code, but for which there is no CPT code. We have used G codes for laboratory tests that do not have CPT codes but for which we make payment, or in situations where we want to treat the codes differently from the CPT code descriptor for Medicare payment purposes.

2. Coding under PAMA

Section 1834A(e) of the Act includes three provisions that relate to coding: (a) Temporary codes for certain new tests; (b) coding for existing tests; and (c) establishment of unique identifiers for certain tests. The effect of section 1834A(e) of the Act is to require the Secretary to establish codes, whereas prior to the enactment of PAMA, the Secretary had discretion to establish codes, but was not required to do so. Before we discussed each of the three provisions in the proposed rule, we addressed several specific references in the statute that we believed needed clarification.

In the three coding provisions, the statute requires us to "adopt," "assign," and "establish" codes or identifiers. We believe those terms to be interchangeable. There is no practical difference between them for purposes of CMS's obligation under section 1834A(e) of the Act, which is, essentially, to ensure that certain laboratory tests can be identified by a HCPCS code, or in the case of section 1834A(e)(3) of the Act, a unique identifier. The statute also refers to "new laboratory tests" and "existing clinical diagnostic laboratory test[s]" in sections 1834A(e)(1)(A) and (2), respectively. We believe new laboratory tests here refers to CDLTs (that are cleared or approved by the FDA) paid under the CLFS on or after January 1, 2017, and existing CDLTs refers to CDLTs (that are cleared or approved by the FDA) paid under the CLFS prior to that date.

a. Temporary Codes for Certain New Tests

Section 1834A(e)(1)(A) of the Act requires the Secretary to adopt temporary HCPCS codes to identify new ADLTs and new laboratory tests that are cleared or approved by the FDA. As discussed previously, we proposed a definition for new ADLTs, and we also discussed what it means for a laboratory test to be cleared or approved by the FDA. We applied those interpretations in this section. We understood the statute to be requiring us to adopt temporary HCPCS level II codes for these two types of laboratory tests if they have not already been assigned a HCPCS code. Therefore, we stated we would use the existing HCPCS coding process for these tests. This means, if a new ADLT or a new CDLT that is FDA-cleared or -approved is not already assigned a CPT code or HCPCS level II code, we would assign a G code to the test. The statute further directs that the temporary code be effective for up to 2 years until a permanent HCPCS code is established, although the statute permits the Secretary to extend the length of time as appropriate. Therefore, we indicated that any G code that we adopt under this provision would be effective for up to 2 years, unless we believed it appropriate to continue to use the G code. For instance, we may create a G code to describe a test for prostate specific antigen (PSA) that may be covered by Medicare under sections 1861(s)(2)(P) and 1861(oo)(2)(B) of the Act as a prostate cancer screening test. At the end of 2 years, if the AMA has not created a CPT code to describe that test but Medicare continues to have a need to pay for the test described by the G code, we would continue to use the G code.

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: Many commenters recommended that, whenever available, CMS utilize the existing HCPCS codes created and assigned by the CPT Editorial Panel for new tests on the CLFS. Commenters explained that private payors often do not recognize G codes assigned by Medicare and that the use of G codes may confuse the billing process and collection of private payor data should private payors use different codes for the same tests. Some commenters stated that a two-step coding process (that is, a temporary G code first, then a permanent CPT code) for new ADLTs would be unnecessarily burdensome for both CMS and clinical laboratories. Commenters also suggested that a quarterly process for assigning permanent codes to ADLTs would be more efficient and lead to more accurate coding and data reporting than the G code process outlined by CMS in the proposed rule.

Response: We understand the commenters' concerns and are clarifying in this final rule that we will use existing HCPCS level I codes created by the CPT Editorial Panel whenever possible. As discussed above in this section, decisions regarding the addition, deletion, or revision of CPT codes are currently made annually by the AMA. CMS does not have authority to change the AMA's annual process to a quarterly process. As has been our standard practice, we expect to use G codes only when CPT codes are unavailable or do not meet our coding needs. In the event that we will need to assign a new G code to an ADLT, or to a CDLT that is cleared or approved by the FDA, we will make such assignments on a quarterly basis, consistent with our current process for updating HCPCS codes. Any temporary HCPCS code will be considered for replacement by a permanent CPT code when it is made available by the AMA, and if it satisfies our coding and payment needs, as part as the annual laboratory public meeting process discussed in section I.B.1 of this final rule.

b. Coding and Publication of Payment Rates for Existing Tests

Section 1834A(e)(2) of the Act stipulates that not later than January 1, 2016, for each existing ADLT and each existing CDLT that is cleared or approved by the FDA for which payment is made under Medicare Part B as of PAMA's enactment date (April 1, 2014), if such test has not already been assigned a unique HCPCS code, the Secretary shall (1) assign a unique HCPCS code for the test and (2) publicly report the payment rate for the test.

As with the requirement for us to adopt codes for certain new tests under section 1834A(e)(1) of the Act, we discussed in the proposed rule that we believed our existing coding process is consistent with the requirements of section 1834A(e)(2) of the Act. Accordingly, we stated that we would use the existing HCPCS coding process for these tests, meaning, if an existing ADLT or existing CDLT is not already assigned a CPT code or a HCPCS level II code, we would assign a G code to the test.

One aspect of section 1834A(e)(2) of the Act (applying to existing tests) that is different than section 1834A(e)(1) of the Act (applying to certain new tests) is the requirement for us to assign a "unique" HCPCS code. We explained in the proposed rule that we understand a unique HCPCS code to describe only a single test. An ADLT is a single test, so each existing ADLT would be assigned its own G code. However, it is possible that one HCPCS code may be used to describe more than one existing CDLT that is cleared or approved by the FDA. For instance, explained in the proposed rule, we understand there are different versions of laboratory tests for the Kirsten rat sarcoma viral oncogene homolog (KRAS)—one version that is FDA-approved and others that are not FDA-cleared or -approved. Currently, the same HCPCS code is used for both the FDA-approved laboratory test for KRAS and the non-FDA-cleared or -approved versions of the test. Thus, the current HCPCS code is not unique in describing only the FDA-approved version of the KRAS test. Under section 1834A(e)(2) of the Act, we are required to ensure that FDA-cleared or -approved versions of the KRAS test are assigned their own unique codes.

As we discussed in the proposed rule, section 1834A(e)(2)(B) of the Act requires us to publicly report the payment rate for existing ADLTs or tests that are cleared or approved by the FDA by January 1, 2016. We noted that we did not meet the deadline for this requirement as we would have established by January 1, 2016 the final definition of an ADLT, an ADLT application process, and a process for identifying FDA-cleared or -approved tests. In section II.D. of this final rule we stated, in response to comments, that we are moving the implementation date of the private payor rate-based CLFS to January 1, 2018. Consistent with this change in implementing the new CLFS payment rates, we believe it is appropriate to adopt a corresponding change in assigning and publicly reporting the payment rates for existing ADLTs and tests that are cleared or approved by the FDA. Therefore, by January 1, 2017, we will assign and publish payment rates for existing ADLTs and tests cleared or approved by the FDA. We will publish the ADLT application process and the process for specifying that a test is cleared or approved by the FDA in subregulatory guidance.

It is possible there are existing ADLTs or CDLTs cleared or approved by the FDA that are currently being priced under our existing regulations using crosswalking or gapfilling. For instance, some tests are currently being priced using gapfilling (see *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2015-CLFS-Codes-Final-Determinations.pdf*). If any of the tests that are currently being priced using gapfilling fall within the category of existing laboratory tests under section 1834A(e)(2) of the Act, we will be able to report the payment rate for them by January 1, 2017. To fulfill the requirement to publicly report payment rates, we will include the codes and payment amounts on the electronic CLFS payment file that we will make available on the CMS Web site prior to January 1, 2017. We are currently considering how we would present the information. We expect to provide a separate field with a special identifier indicating when a HCPCS code uniquely describes an existing laboratory test, although we may separately identify those codes that uniquely identify an existing test in separate documentation describing the file.

Comment: A few commenters recommended that we not assign unique codes to tests if they already have a code that is being billed to Medicare. The commenters advised against assigning unique codes to every FDA-cleared or -approved test as this could result in duplicative coding efforts. Thus, commenters believed a CDLT with FDA clearance or approval should not receive a unique HCPCS code. One commenter stated that there is no clinical or economic rationale for us to use our current coding process to differentiate between FDA-cleared or -approved tests and non-FDA-cleared or -approved tests. The commenter explained there may be unintended consequences of generating these codes ahead of any further actions from the FDA with regard to the oversight of laboratory tests. In addition, the commenter suggested that it is not apparent from the statute that an FDA-cleared or -approved CDLT should not share its code with a clinically equivalent non-FDA-cleared or -approved CDLT, nor that doing so would be inconsistent with the requirements under section 1834A(e) of the Act. Some commenters also suggested that if we do assign unique codes for FDA-cleared or -approved tests, then we should establish the temporary HCPCS code through public notice and comment rulemaking to allow for transparency and multi-stakeholder input. A few commenters recommended that, rather than doing so automatically, we should assign a unique HCPCS code for an ADLT or an FDA-cleared or -approved test only when a laboratory or manufacturer requests a unique code.

Response: We understand the commenters' concerns regarding assigning unique codes to an FDA-cleared or -approved version of a test. However, as we discussed in this section, the statute requires the Secretary to adopt a unique HCPCS code for each existing ADLT and each new CDLT that is cleared or approved by the FDA if such tests are not already assigned a unique HCPCS code, and we view "unique" in this context to mean a HCPCS code that describes only a single test. We agree that our assignment of such codes should be done with transparency and multi-stakeholder input. As these codes would be new for the CLFS, they would be subject to the CLFS annual public meeting process, which provides for a public review and comment period for new and reconsidered tests (for more detail on this process, see section I.B.1 of this final rule). We believe our current CLFS public process, which is required to continue under section 1834A(e)(3) of the Act, will sufficiently address the public's needs for transparency and input in the assignment of unique codes for these tests. Therefore, we do not agree that the assignment of HCPCS codes for this purpose should be subject to notice and comment rulemaking.

To alleviate commenters' concerns that we will automatically assign a unique HCPCS code for an ADLT or an FDA-cleared or -approved test, we note that laboratories must first indicate to the agency that its test requires a unique code. We may not be aware of existing ADLTs or CLDTs that are cleared or approved by the FDA that do not already have a unique HCPCS code. Details regarding how laboratories must notify us will be specified in subregulatory guidance.

c. Establishing Unique Identifiers for Certain Tests

Section 1834A(e)(3) of the Act requires the establishment of a unique identifier for certain tests. Specifically, section 1834A(e)(3) of the Act provides that, for purposes of tracking and monitoring, if a laboratory or a manufacturer requests a unique identifier for an ADLT or a laboratory test that is cleared or approved by the FDA, the Secretary shall use a means to uniquely track such test through a mechanism such as a HCPCS code or modifier. Section 1834A(e)(3) of the Act applies only to those laboratory tests that are addressed by sections 1834A(e)(1) and (2) of the Act, that is, new and existing ADLTs and new and existing CDLTs that are cleared or approved by the FDA.

The statute does not define "tracking and monitoring." However, in the context of a health insurance program like Medicare, tracking and monitoring would typically be associated with enabling or facilitating the obtaining of information included on a Medicare claim for payment to observe such factors as: Overall utilization of a given service; regional utilization of the service; where a service was provided (for example, office, laboratory, hospital); who is billing for the service (for example, physician, laboratory, other supplier); which beneficiary received the service; and characteristics of the beneficiary receiving the service (for example, male/female, age, diagnosis). As the HCPCS code is the fundamental variable used to identify an item or service, and can serve as the means to uniquely track and monitor many various aspects of a laboratory test, we believed the requirements of this section would be met by the existing HCPCS coding process. Therefore, we proposed to implement section 1834A(e)(3) of the Act using our current HCPCS coding system, which we are finalizing in this final rule. If a laboratory or manufacturer specifically requests a unique identifier for tracking and monitoring an ADLT or an FDA-cleared or -approved CDLT, we will assign it a unique HCPCS code if it does not already have one.

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: A few commenters recommended that we implement a more granular coding structure than the HCPCS coding processes for tests on the CLFS. Specifically, they suggested we use the McKesson Z codes which, they explained, provide granularity to the level of the specific laboratory that furnishes the test. The commenters mentioned that our contractor for the MolDx program and several private payors already utilize Z codes and suggest they can be adapted to our needs for assigning unique identifiers for certain tests, as required under section 1834A(e)(3) of the Act.

Response: We believe our current HCPCS coding processes will sufficiently meet our coding needs under section 1834A(e)(3) of the Act. We also note that, as of this final rule, the McKesson Z codes are not a HIPAA-compliant code set; HCPCS and CPT–4 are the current medical data code set standards adopted for use in health care claims transactions for physician and other health care services, such as CDLTs (see 42 CFR 162.1000 and 162.1002).

Comment: One commenter requested to be allowed to assist us in the ADLT application process and to be involved with the coding of new ADLTs.

Response: We appreciate the commenter's offer of assistance in the matter of designating a test as an ADLT and coding new ADLTs. We plan to consider recommendations of the CDLT Advisory Panel (see the discussion of the Panel in section II.J.1. of this final rule) as part of the process for determining ADLT status and assigning an ADLT a unique code. Meetings of the Panel are open to the public and input from the public is welcome. Announcements of the Panel meetings are published in the **Federal Register** and meeting agendas are posted on CMS's CLFS Web site at: *https://www.cms.gov/Regulations-and-Guidance/*

Guidance/FACA/AdvisoryPanelon ClinicalDiagnosticLaboratoryTests.html.

H. Payment Methodology

1. Calculation of Weighted Median

Section 1834A(b) of the Act establishes a new methodology for determining Medicare payment amounts for CDLTs on the CLFS. Section 1834A(b)(1)(A) of the Act establishes the general requirement that the Medicare payment amount for a CDLT furnished on or after January 1, 2017, shall be equal to the weighted median determined for the test for the most recent data collection period. Section 1834A(b)(2) of the Act requires the Secretary to calculate a weighted median for each laboratory test for which information is reported for the data collection period by arraying the distribution of all private payor rates reported for the period for each test weighted by volume for each private payor and each laboratory. As discussed later in this section, the statute includes special payment requirements for new ADLTs and new CDLTs that are not ADLTs.

To illustrate how we proposed to calculate the weighted median for CDLTs, we provided examples of several different scenarios in the proposed rule (80 FR 59404 through 59406). These examples showed how we planned to determine the weighted median and were not exhaustive of every possible pricing scenario. In the first example, as depicted in Table 6, we supposed that the following private payor rate and volume information for three different CDLTs was reported for applicable laboratories.

TABLE 6—EXAMPLE OF THE CALCULATION OF THE WEIGHTED MEDIAN

	Test 1		Test 2		Test 3	
	Private payor rate	Volume	Private payor rate	Volume	Private payor rate	Volume
Lab. A	$5.00	1,000	$25.00	500	$40.00	750
Lab. B	9.00	1,100	20.00	2,000	41.00	700
Lab. C	6.00	900	23.50	1,000	50.00	500
Lab. D	2.50	5,000	18.00	4,000	39.00	750
Lab. E	4.00	3,000	30.00	100	45.00	850

In this example, there are five different private payor rates for each test. Table 6 is shown again as Table 7 with each test arrayed by order of the lowest to highest private payor rate, with each private payor rate appearing one time only so as to not reflect volume weighting.

TABLE 7—EXAMPLE OF THE CALCULATION OF THE UNWEIGHTED MEDIAN

	Test 1	Test 2	Test 3
	Private payor rate	Private payor rate	Private payor rate
Lowest (1)	$2.50	$18.00	$39.00
Next in Sequence (2)	4.00	20.00	40.00
Next in Sequence (3)	5.00	23.50	41.00
Next in Sequence (4)	6.00	25.00	45.00
Highest (5)	9.00	30.00	50.00

With five different private payor rates for each test, the unweighted median is the middle value or the third line in the table where there are an equal number of private payor rates listed above and below the third line in the table. The *unweighted* median private payor rate for each test would be:

- Test 1 = $5.00
- Test 2 = $23.50
- Test 3 = $41.00

These results are obtained by arraying the distribution of all private payor rates reported for the period for each test without regard to the volume reported for each private payor and each laboratory. To obtain the weighted median, we would do a similar array to the one in Table 7 except we would list each distinct private payor rate repeatedly by the same number of times as its volume. This is illustrated for Test 1 in Table 8.

TABLE 8—EXAMPLE OF THE CALCULATION OF THE WEIGHTED MEDIAN

	Test 1
	Private payor rate
Lowest (1)	$2.50
Lowest (2)	2.50
. . .	2.50
. . .	2.50
Until . . . (5,000)	2.50
Next Rate in Sequence (5,001)	4.00
Next Rate in Sequence (5,002)	4.00
. . .	4.00
. . .	4.00
Until (8,000)	4.00
. . .	. . .
Highest (11,000)	9.00

Thus, for Test 1, the array would show the lowest private payor rate of $2.50 five thousand times. The ellipsis (". . .") represents the continuation of the sequence between lines 2 and 4,999. The next private payor rate in the sequence ($4.00) would appear on line 5,001 and would be listed 3,000 times until we get to line 8,000. This process would continue with the remaining private payor rates listed as many times as the associated volumes, with the continuing sequence illustrated by ellipses. Continuing the array, the next highest private payor rate in the sequence would be: $5.00 listed 1,000 times; $6.00 listed 900 times; and $9.00 listed 1,100 times. The total number of lines in the array would be 11,000, as that is the total volume for Test 1 furnished for the five applicable laboratories. Because the total volume for Test 1 is 11,000, the weighted median private payor rate would be the average of the 5,500th and 5,501st entry, which would be $4.00.

Repeating this process for Test 2 (see Table 9), the total volume for Test 2 is 7,600 units; therefore, the weighted median private payor rate would be the average of the 3,800th and 3,801st entry, which would be $18.00.

TABLE 9—TEST 2—SORTED BY RATE

Private payor rate	Volume
$18.00	4,000
20.00	2,000
23.50	1,000
25.00	500
30.00	100

For Test 3 (see Table 10), the total volume is 3,550 units; therefore, the weighted median private payor rate would be the average of the 1,775th and 1,776th entry, which would be $41.00.

TABLE 10—TEST 3—SORTED BY RATE

Private payor rate	Volume
$39.00	750
40.00	750
41.00	700
45.00	850
50.00	500

In this example, weighting changed the median private payor rate from $5.00 to $4.00 for Test 1, from $23.50 to $18.00 for Test 2, and resulted in no change ($41.00 both unweighted and weighted) for Test 3.

For simplicity, the above example shows only one private payor rate per test. We expect laboratories commonly have multiple private payor rates for each CDLT they perform. For each test performed by applicable laboratories having multiple private payor rates, we would use the same process shown above in this section, irrespective of how many different private payor rates there are for a given test. That is, we would list each private payor rate and its volume at that private payor rate, and determine the median as we did above for each payor and each laboratory, and then compute the volume-weighted median rate. The following example in Table 11 illustrates how we proposed to calculate the weighted median rate for a test under this scenario:

TABLE 11—TEST 4

	Payor 1		Payor 2		Payor 3	
	Private payor rate	Volume	Private payor rate	Volume	Private payor rate	Volume
Lab. A	$5.00	10	$5.25	20	$4.00	30
Lab. B	3.75	50				
Lab. C	6.00	5	5.00	10	5.50	25
Lab. D	5.00	10	4.75	30		
Lab. E	6.00	5				

To calculate the weighted median for Test 4, we would array all private payor rates, listed the number of times for each respective test's volume, and then determine the median value (as illustrated in Table 12).

TABLE 12—TEST 4—SORTED BY RATE

Private payor rate	Volume
$3.75	50
4.00	30
4.75	30
5.00	10
5.00	10
5.00	10
5.50	25
5.25	20
6.00	5
6.00	5

The total volume for Test 4 is 195. Therefore, the median value would be at the 98th entry, which would be $4.75. We proposed to describe this process in § 414.507(b).

Section 1834A(b)(1)(B) of the Act states that the Medicare payment amounts established under section 1834A of the Act shall apply to a CDLT furnished by a hospital laboratory if such test is paid for separately, and not as part of a bundled payment under section 1833(t) of the Act (the statutory section pertaining to the OPPS). In CY 2014, we finalized a policy to package certain CDLTs in the OPPS (78 FR 74939 through 74942 and § 419.2(b)(17)). Under current policy, certain CDLTs that are listed on the CLFS are packaged in the OPPS as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting on the same date of service as the laboratory test. Specifically, we conditionally package laboratory tests and only pay separately for a laboratory test when (1) it is the only service provided to a beneficiary on a given date of service or (2) it is conducted on the same date of service as the primary service, but is ordered for a different purpose than the primary service and ordered by a practitioner different than the practitioner who ordered the other OPPS services. Also excluded from this conditional packaging policy are molecular pathology tests described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479 (78 FR 74939 through 74942). When laboratory tests are not packaged under the OPPS and are listed on the CLFS, they are paid at the CLFS payment rates outside the OPPS under Medicare Part B. Section 1834A(b)(1)(B) of the Act would require us to pay the CLFS payment amount determined under section 1834A(b)(1)(B) of the Act for CDLTs that are provided in the hospital outpatient department and not packaged into Medicare's OPPS payment. This policy would apply to any tests currently paid separately in the hospital outpatient department or in the future if there are any changes to OPPS packaging policy.[2] As these are payment policies that pertain to the OPPS, we would implement them in OPPS annual rulemaking.

Next, section 1834A(b)(4)(A) of the Act states that the Medicare payment amounts under section 1834A(b) shall continue to apply until the year following the next data collection period. We proposed to implement this requirement in proposed § 414.507(a) by stating that each payment rate will be in effect for a period of 1 calendar year for ADLTs and 3 calendar years for all other CDLTs, until the year following the next data collection period.

Section 1834A(b)(4)(B) of the Act states that the Medicare payment amounts under section 1834A of the Act shall not be subject to any adjustment (including any geographic adjustment, budget neutrality adjustment, annual update, or other adjustment). The new payment methodology for CDLTs established under section 1834A(b) of the Act will apply to all tests furnished on or after January 1, 2018 (the revised implementation date we are adopting for the private payor rate-based CLFS) and replace the current methodology for calculating Medicare payment amounts for CDLTs under sections 1833(a), (b), and (h) of the Act, including the annual updates for inflation based on the percentage change in the CPI–U and reduction by a multi-factor productivity adjustment (see section 1833(h)(2)(A) of the Act). We stated in the proposed rule that we believed section 1834A(b)(4)(B) of the Act is clear that no annual update adjustment shall be applied for tests paid under section 1834A of the Act. Therefore, we proposed to include in § 414.507(c) that the payment amounts established under this section are not subject to any adjustment, such as any geographic, budget neutrality, annual update, or other adjustment.

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[2] For the CY 2016 OPPS final rule, we adopted changes to the packaging policy described above. See 80 FR 70348 for more information.

A discussion of the public comments we received regarding the calculation of the weighted median private rate, and our responses to those comments, appears below.

Comment: Many commenters agreed with the calculation of the weighted median private payor rate outlined in the proposed rule but expressed concern about whether the calculated weighted median prices would reflect "true market rates" for laboratory services. For example, many commenters believed PAMA intended to include data from independent laboratories and hospital outreach laboratories when calculating the weighted median private payor rate for each laboratory test. Additionally, commenters contended that "true market-based reimbursement rates" can be calculated by defining an applicable laboratory as an entity identified by a CLIA number and not by TIN. To that end, the commenters recommended CMS revise the definition of applicable laboratory as an entity identified by a CLIA number so that independent laboratories and hospital outreach laboratories are included in the calculation of the weighted median private payor rates.

Response: In section II.A. of this final rule, we explain that we are defining applicable laboratory in terms of the NPI rather than the TIN and specifying in the definition that the majority of Medicare revenues threshold and the low expenditure threshold are to be applied by the NPI-level entity rather than by the TIN-level entity collectively with all its associated NPIs. A primary benefit of defining applicable laboratory at the NPI level, rather than at the TIN level, is that it will not prevent hospital outreach laboratories from meeting the definition of applicable laboratory and, therefore, reporting private rates. We also explained that we are not defining applicable laboratory by the CLIA certificate, in part, because CLIA certificates are not associated with Medicare billing so, unlike the NPI, with which revenues for specific services can easily be identified, the CLIA certificate cannot be used to identify revenues for specific services.

Independent laboratories that exceed the majority of Medicare revenues threshold and the low expenditure threshold will meet the definition of applicable laboratory and their applicable information will be reported to us for determining the weighted median private payor rate. Although the low expenditure threshold will exclude many independent laboratories and physician office laboratories from reporting private payor rates, based on our analysis of CY 2013 CLFS claims data, we found with a $12,500 threshold for a 6-month data collection period, we can retain a high percentage of Medicare FFS utilization data under the CLFS from applicable laboratories. We note that because CLFS payments will be based on the weighted median of private payor rates, additional reporting may not be likely to change the weighted median private payor rate, irrespective of how many additional smaller laboratories are required to report, if, as our analysis suggests, the largest laboratories dominate the market and therefore most significantly affect the payment rate. For more information regarding the definition of applicable laboratory, please see section II.A. of this final rule.

Comment: A few commenters requested that we calculate a weighted median private payor rate with and without data from Medicaid managed care organizations. These commenters opined that the effect of the inclusion of Medicaid managed care plans as private payors under the Act and their corresponding payment rates in the calculation of the weighted median is not yet fully known. They further indicated that determining the weighted median with and without Medicaid managed care plans will help us to assess the effect of setting Medicaid rates at a percentage of Medicare payment amounts over time.

Response: The statute requires the payment amount for laboratory tests paid under the new CLFS to be equal to the weighted median of private payor rates, and it explicitly includes in the definition of private payor, at section 1834A(a)(8)(c), Medicaid managed care organizations. Therefore, we do not believe we can apply a weighted median private payor rate for a test that we calculate without Medicaid managed care organization rates.

Comment: Two commenters requested clarification as to how we would address updating payment rates for tests which previously had multiple laboratories reporting private payor rates, but for which, in a subsequent data reporting period data is submitted by only one laboratory with low volume for the test. The commenters expressed concern that the updated payment rates would be based on a non-statistically significant amount of data reported for a test code(s). To that end, the commenters requested we ensure that a weighted median private payor rate represents data from more than one laboratory.

Response: Section 1834A(b)(2) of the Act requires the Secretary to calculate a weighted median private payor rate for each laboratory test for which information is reported for the data collection period by arraying the distribution of all private payor rates reported for the period for each test weighted by volume for each private payor and each laboratory. Section 1834A(b)(1)(A) of the Act requires the payment to be equal to the weighted median private payor rate for the test for the most recent data collection period. We do not see where the statute would permit us to deviate from that prescribed methodology in the situation where all the applicable information we receive for a test is reported by only one laboratory. Furthermore, in this final rule, we note that the statute specifies that only a single laboratory may offer and furnish an ADLT. Although for purposes of an ADLT we are revising the definition of a single laboratory to include entities that own or are owned by a laboratory, a single laboratory could conceivably consist of only one laboratory. Therefore, we cannot ensure that any data used to calculate a weighted median private payor rate represents more than one laboratory's private payor rate data.

Comment: One commenter requested clarification as to whether the new CLFS will have a national fee schedule amount for each laboratory test code or if the payment amounts will be adjusted locally by the MACs. The commenter also requested that we clarify whether the median private payor rate will be calculated from applicable information reported for tests furnished only to Medicare beneficiaries or will include private payor rates of tests furnished to commercial beneficiaries as well.

Response: Section 1834A(b)(4)(B) of the Act prohibits geographic adjustments of the new CLFS payment amounts. Therefore, the payment amounts under the revised CLFS will reflect a national fee schedule amount for each test. We also clarify that the applicable information reported is not limited to private payor rates for laboratory tests furnished to Medicare beneficiaries. Private payors, as we define the term at § 414.502, include health insurers, group health plans, Medicare Advantage plans, and Medicaid managed care organizations.

2. Phased-In Payment Reduction

Section 1834A(b)(3) of the Act limits the reduction in payment amounts that may result from implementation of the new payment methodology under section 1834A(b) of the Act within the first 6 years. Specifically, section 1834A(b)(3)(A) of the Act states that the payment amounts determined for a CDLT for a year cannot be reduced by more than the applicable percent from the preceding year for each of 2017 through 2022. Under section 1834A(b)(3)(B) of the Act, the applicable percent is 10 percent for each of 2017 through 2019, and 15 percent for each of 2020 through 2022. These provisions do not apply to new ADLTs, or new CDLTs that are not ADLTs.

In the proposed rule (80 FR 59407), we provided the following example. If a test that is not a new ADLT or new CDLT has a CY 2016 Medicare payment amount of $20.00, the maximum reduction in the Medicare payment amount for CY 2017 is 10 percent, or $2. Following the CY 2016 data reporting period, CMS calculates a weighted median of $15.00 (a reduction of 25 percent from a Medicare payment amount of $20.00) based on the applicable information reported for the test. Because the maximum payment reduction permitted under the statute for 2017 is 10 percent, the Medicare payment amount for CY 2017 will be $18.00 ($20.00 minus $2.00). The following year, a 10 percent reduction from the CY 2017 payment of $18.00 would equal $1.80, lowering the total Medicare payment amount to $16.20 for CY 2018. In a second example we provided, if a test that is not a new ADLT or new CDLT has a CY 2016 Medicare payment amount of $17.00, the maximum reduction for CY 2017 is 10 percent or $1.70. Following the CY 2016 data reporting period, we calculated a weighted median of $15.00 (a reduction of 11.8 percent from the CY 2016 Medicare payment amount of $17). Because the maximum reduction is 10 percent, the Medicare payment amount for CY 2017 will be $15.30 or the maximum allowed reduction of $1.70 from the preceding year's (CY 2016) Medicare payment amount of $17.00. The following year (CY 2018), the Medicare payment amount will be reduced to $15.00, or $0.30 less, which is less than a 10 percent reduction from the prior year's (CY 2017) Medicare payment amount of $15.30. We believed applying the maximum applicable percentage reduction from the prior year's Medicare payment amount, rather than from the weighted median rate for CY 2016, was most consistent with the statute's mandate that the reduction "for the year" (that is, the calendar year) not be "greater than the applicable percent . . . of the amount of payment for the test for the preceding year."

We explained in the proposed rule that, to apply the phase-in reduction provisions beginning in CY 2017, we must look at the CLFS rates established for CY 2016 under the payment methodology set forth in sections 1833(a), (b), and (h) of the Act. Previously discussed, CDLTs furnished on or after July 1, 1984, and before January 1, 2017, in a physician's office, by an independent laboratory, or, in limited circumstances, by a hospital laboratory for its outpatients or non-patients, are paid under the Medicare CLFS, with certain exceptions. Payment is the lesser of:

- The amount billed;
- The state or local fee schedule amount established by Medicare contractors; or
- An NLA, which is a percentage of the median of all the state and local fee schedules.

The NLA is 74 percent of the median of all local Medicare payment amounts for tests for which the NLA was established before January 1, 2001. The NLA is 100 percent of the median of the local fee schedule amount for tests for which the NLA was first established on or after January 1, 2001 (see section 1833(h)(4)(B)(viii) of the Act). Medicare typically pays either the lower of the local fee schedule amount or the NLA, as it uncommon for the amount billed to be less than either of these amounts. As the local fee schedule amount may be lower than the NLA, Medicare payment amounts for CDLTs are not uniform across the nation. Thus, in the proposed rule we evaluated which CY 2016 CLFS payment amounts to consider—the lower of the local fee schedule amount or the NLA, or just the NLA—when applying the phase-in reduction provisions to the CLFS rates for CY 2017 (80 FR 59407). Under option 1, we explained we would apply the 10 percent reduction limitation to the lower of the NLA or the local fee schedule amount. This option would retain some of the features of the current payment methodology under sections 1833(a), (b), and (h) of the Act and, we believed, would be the most consistent with the requirement in section 1834A(b)(3)(A) of the Act to apply the applicable percentage reduction limitation to the "amount of payment for the test" for the preceding year. As noted above, for each of CY 2018 through 2022, we explained we would apply the applicable percentage reduction limitation to the Medicare payment amount for the preceding year. Under this option, though, the Medicare payment amounts may be local fee schedule amounts, so there could continue to be regional variation in the Medicare payment amounts for CDLTs.

Alternatively, under option 2, we explained would consider only the NLAs for CY 2016 when applying the 10 percent reduction limitation. This option would eliminate the regional variation in Medicare payment amounts for CDLTs, and, we believed, would be more consistent with section 1834A(b)(4)(B) of the Act, which, as noted above, prohibits the application of any adjustments to CLFS payment amounts determined under section 1834A of the Act, including any geographic adjustments.

We proposed option 2 (NLAs only) for purposes of applying the 10 percent reduction limit to CY 2017 payment amounts because we believed the statute intends CLFS rates to be uniform nationwide, which is why it precludes any geographic adjustment. That is, we proposed that if the weighted median calculated for a CDLT based on applicable information for CY 2017 would be more than 10 percent less than the CY 2016 NLA for that test, we would establish a Medicare payment amount for CY 2017 that is no less than 90 percent of the NLA (that is, no more than a 10 percent reduction). For each of CY 2018 through 2022, we would apply the applicable percentage reduction limitation to the Medicare payment amount for the preceding year.

We proposed to codify the phase-in reduction provisions in § 414.507(d) to specify that for years 2017 through 2022, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

- 2017—10 percent of the NLA for the test in 2016.
- 2018—10 percent of the payment rate established in 2017.
- 2019—10 percent of the payment rate established in 2018.

- 2020—15 percent of the payment rate established in 2019.
- 2021—15 percent of the payment rate established in 2020.
- 2022—15 percent of the payment rate established in 2021.

Table 13 illustrates the proposed phase-in reduction for the two hypothetical examples presented above:

TABLE 13—PHASE-IN REDUCTION FOR 2 EXAMPLES

	NLA	Private payor rate	10% maximum reduction	2017 rate	10% maximum reduction	2018 rate	10% maximum reduction	2019 rate
Test 1	$20.00	$15.00	$2.00	$18.00	$1.80	$16.20	$1.20 < 10%	$15.00
Test 2	17.00	15.00	1.70	15.30	0.30 < 10%	15.00	0.00 < 10%	15.00

Revised Phase-In of Payment Reduction Timetable

As discussed in section II.D., we are moving the implementation date of the private payor-based rates for the CLFS to January 1, 2018. We are finalizing our proposed policy for the phase-in of payment reductions, but we believe it is appropriate to make a corresponding change to the phase-in payment reduction timetable, which will permit laboratories to get the full benefit of the payment reduction limitations we believe the statute intended. Accordingly, we are revising the phase-in of the payment reductions timetable to reflect the January 1, 2018 implementation date of the revised CLFS. We are reflecting this change in § 414.507(d) by indicating that a maximum payment reduction per year of 10 percent applies for years 2018 through 2020 and a maximum payment reduction per year of 15 percent applies for years 2021 through 2023.

A discussion of the comments we received on the phase-in payment reduction, and our responses to those comments, appears below.

Comment: Two commenters requested clarification as to whether we would publish the full phased-in payment reductions, through CY 2022, when we publish the preliminary CLFS payment rates, or whether we would only publish the adjustment that would apply in January of the following year. The commenters believe it is important for laboratories to understand how payment reductions are applied to current Medicare payment rates over a three-year period to support laboratory planning over the course of several years.

Response: Under the private payor rate-based CLFS, the preliminary payment amounts we publish in September will reflect the full median private payor rate for each CDLT for a given update for the next calendar year. For example, if a test that is not a new ADLT or new CDLT has a CY 2017 national limitation amount (NLA) of $20.00, and we calculate a weighted median private payor rate of $15.00 following the CY 2017 data reporting period, the preliminary payment amount for CY 2018 would be $15.00 for the test. Laboratories will have the opportunity to review the fully phased-in payment reduction for a given CLFS update from the preliminary CLFS payment file. However, the final payment file published in November will only reflect the application of the phased-in payment reduction for the next calendar year.

Comment: One commenter requested clarification as to whether we will apply a maximum amount that a laboratory test's payment rate may increase over six years since there is a six-year limitation on the decrease, and whether we anticipate that laboratory rates will decrease in all circumstances. The commenter also requested clarification as to why the maximum decrease per year is needed.

Response: We are applying a phased-in payment reduction limitation as required by section 1834A(b)(3) of the Act. While the statute limits the amount of the payment reduction for laboratory tests, it does not limit the amount by which a laboratory test's payment rate may increase under the new CLFS, so we are not applying a limit on the increase amount. We cannot anticipate, as the commenter requested, whether payment rates for laboratory tests paid under the private payor rate-based CLFS will decrease in all circumstances. We note that, as discussed in the proposed rule (80 FR 59416), a study by the Office of Inspector General, "Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings" (OEI–07–11–00010, June 2013), showed Medicare paid between 18 and 30 percent more than other insurers for 20 high-volume and/or high-expenditure lab tests. We assumed the private payor rates to be approximately 20 percent lower than the Medicare CLFS payment rates for all tests paid under the CLFS. However, this aggregate assumption cannot be used to estimate the change in payment rates resulting from the private payor rate-based CLFS for a specific test(s).

3. Payment for New ADLTs

Section 1834A(d)(1)(A) of the Act provides that the payment amount for a new ADLT shall be based on the actual list charge for the laboratory test during an initial period of 3 quarters. Section 1834A(d)(2) of the Act requires applicable information to be reported for a new ADLT not later than the last day of the Q2 of the initial period. Section 1834A(d)(3) of the Act requires the Secretary to use the weighted median methodology under section (b) to establish Medicare payment rates for new ADLTs after the initial period. Under section 1834A(d)(3) of the Act, such payment rates continue to apply until the year following the next data collection period.

In this section, we discussed our proposal to require the initial period, which we proposed to call the "new ADLT initial period," to begin on the first day of the first full calendar quarter following the first day on which a new ADLT is performed. In accordance with section 1834A(d)(1)(A) of the Act, we proposed that the payment amount for the new ADLT would equal the actual list charge, as defined below in this section, during the new ADLT initial period. Accordingly, we proposed to codify § 414.522(a)(1) to specify the payment rate for a new ADLT during the new ADLT initial period is equal to its actual list charge.

Section 1834A(d)(1)(B) of the Act states that actual list charge means the publicly available rate on the first day at which the test is available for purchase by a private payor for a laboratory test. We believed the "publicly available rate" is the amount charged for an ADLT that is readily accessible in such forums as a company Web site, test registry, or price listing, to anyone seeking to know how much a patient who does not have the benefit of a negotiated rate would pay for the test. We noted that this interpretation of publicly available rate is distinguishable from a private payor rate in that the former is readily available to a consumer, while the latter may be negotiated between a private payor and a laboratory and is not readily available to a consumer. We recognized there may be more than one publicly available rate, in which case we believed the lowest rate should be the actual list charge amount so that Medicare is not paying more than the lowest rate that is publicly available to any consumer. We proposed to define publicly available rate in § 414.502 as the lowest amount charged for an ADLT that is readily accessible in such forums as a company Web site, test registry, or price listing, to anyone seeking to know how much a patient who does not have the benefit of a negotiated rate would pay for the test.

We explained in the proposed rule that, in our view, the first day a new ADLT is available for purchase by a private payor is the first day an ADLT is offered to a patient who is covered by private insurance. The statutory phrase "available for purchase" suggested to us that the test only has to be available to patients who have private insurance even if the test has not actually been performed yet by the laboratory. That is, it is the first day the new ADLT is obtainable by a patient, or marketed to the public as a test that a patient can receive, even if the test has not yet been performed on that date. We proposed to incorporate this interpretation into our proposed definition of actual list charge in § 414.502 to specify actual list charge is the publicly available rate on the first day the new ADLT is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date.

Because we cannot easily know the first date on which a new ADLT is performed or the actual list charge amount for a new ADLT, we proposed to require the laboratory seeking ADLT status for its test to inform us of both the date the test is first performed and the actual list charge amount. Accordingly, we proposed in § 414.504(c), that, in its new ADLT application, the laboratory seeking new ADLT status for its test must attest to the actual list charge and the date the new ADLT is first performed. We also indicated that we would outline the new ADLT application process in detail in subregulatory guidance prior to the effective date of the private payor rate based CLFS.

Because the new ADLT initial period starts on the first day of the next calendar quarter following the first day on which a new ADLT is performed, there will be a span of time between when the test is first performed and when the test is paid the actual list charge amount. We indicated in the proposed rule that we need to establish a payment amount for the test during that span of time. We explained that, similar to how we pay for a test under the PFS, the CLFS, or other payment systems, for a service that does not yet have a national payment amount, the MAC would work with a laboratory to develop a payment rate for a new ADLT for the period of time before we pay at actual list charge. We provided the following example in the proposed rule (80 FR 59408). If an ADLT is first performed on February 4, 2017, the new ADLT initial period would begin on April 1, 2017. While the new ADLT would be paid the actual list charge amount from April 1 through December 31, 2017, the MAC would determine the payment amount for the test from February 4 through March 31, 2017, as it does currently for tests that need to be paid prior to having a national payment amount. We proposed to specify at § 414.522(a)(2) that the payment amount for a new ADLT prior to the new ADLT initial period is determined by the MAC based on information provided by the laboratory seeking new ADLT status for its laboratory test.

According to section 1834A(d)(3) of the Act, the weighted median methodology used to calculate the payment amount for CDLTs that are not new ADLTs will be used to establish the payment amount for a new ADLT after the new ADLT initial period; we explained that the payment amount would be based on applicable information reported by an applicable laboratory before the last day of the second quarter of the new ADLT initial period, per section 1834A(d)(2) of the Act. We proposed to codify these provisions in § 414.522(b) as follows: After the new ADLT initial period, the payment rate for a new ADLT is equal to the weighted median established under the payment methodology described in § 414.507(b).

The payment rate based on the first 2 quarters of the new ADLT initial period would continue to apply until the year following the next data collection period, per section 1834A(d)(3) of the Act. The following is the example we provided in the proposed rule (80 FR 59408 through 59409) of how the various time frames for new ADLT payment rates would work. If the first day a new ADLT is available for purchase by a private payor is in the middle of Q1 of 2017, the new ADLT initial period would begin on the first day of Q2 of CY 2017. The test would be paid actual list charge through the end of Q4 of CY 2017. The applicable laboratory that furnishes the test would collect applicable information in Q2 and Q3 of CY 2017, and report it to us by the last day of Q3 of CY 2017. We would calculate a weighted median based on that applicable information and establish a payment rate that would be in effect from January 1, 2018, through the end of 2018. The applicable laboratory would report applicable information from the CY 2017 data collection period to us during the January through March data reporting period in 2018, which would be used to establish the payment rate that would go into effect on January 1, 2019.

A discussion of the comments we received on payment for new ADLTs, and our responses to those comments, appears below.

Comment: Two commenters noted that the statute defines actual list charge as the publicly available rate on the first day at which the test is available for purchase by a private payor. The commenter requested that we adopt that statutory definition, which the commenter believe is clear and gives laboratories sufficient guidance, rather than expand upon the statutory definition of actual list charge.

Response: We believe we need to interpret several phrases in the statutory definition of actual list charge—"publicly available rate" and "available for purchase"—without which the industry would not have a common and consistent understanding of how we are implementing the actual list charge requirement. As discussed in the proposed rule (80 FR 59408), it is our understanding that if a test is "available for purchase," the test does not have to have been performed yet; it only has to be available to patients who have private insurance. Further, our definition of "publicly available rate" in § 414.502 illustrates that we mean the lowest amount charged that is readily accessible to the public.

4. Recoupment of Payment for New ADLTs if Actual List Charge Exceeds Market Rate

Section 1834A(d)(4) of the Act requires that, if the Medicare payment amount during the new ADLT initial period (that is, the actual list charge) is determined to be more than 130 percent of the Medicare payment amount based on the weighted median of private payor rates that applies after the new ADLT initial period, the Secretary shall recoup the difference between such payment amounts for tests furnished during such period.

In the proposed rule, we interpreted this to mean that the Secretary should recoup the entire amount of the difference between the Medicare payment amount during the new ADLT initial period and the Medicare payment amount based on the weighted median of private payor rates—not the difference between the Medicare payment amount during the initial period and 130 percent of the weighted median rate. In the proposed rule, we noted as an example, if the Medicare payment amount using actual list charge is $150 during the new ADLT initial period and the weighted median rate is $100, the Medicare payment amount for the new ADLT initial period is 150 percent of the Medicare payment amount based on the weighted median rate. We believed the statute directed the Secretary to use 130 percent as the threshold for invoking the recoupment provision but once invoked, collect the entire amount of the difference in Medicare payment amounts ($50 in this example).

The statute refers to "such payment amounts" which we interpreted to mean the Medicare payment amount based on actual list charge and the Medicare payment amount based on the weighted median rate. We believed that the statute directed recoupment of the full amount of that difference as the 130 percent is only being used in making the threshold determination of whether the recoupment provision will apply. For this reason, we proposed at § 414.522(c) to specify that if the Medicare payment amount for an ADLT during the new ADLT initial period (based on actual list charge) was more than 130 percent of the weighted median rate, we would recoup the entire amount of the difference between the two amounts. We further noted that if the 130 percent statutory threshold is not exceeded, we would not make any recoupment at all. Thus, for instance, if the weighted median private payor rate is $100 and the Medicare payment amount during the initial period is $130 or lower, the statutory threshold of 130 percent would not be exceeded and we would not pursue any recoupment of payment.

However, if the actual list charge for a new ADLT was more than 130 percent of the weighted median rate (as calculated from applicable information received during the first reporting period), claims paid during the new ADLT initial period would be re-priced using the weighted median rate. To that end, we proposed that we would issue a Technical Direction Letter instructing the MACs to re-price claims previously paid during the new ADLT initial period at the weighted median rate (instead of the actual list charge for the new ADLT). We also noted that we intended to issue further guidance on the operational procedures for recoupment of payments for the new ADLTs that exceed the 130 percent threshold.

A discussion of the comments we received on our proposed recoupment of payment for new ADLTs and our responses to those comments, appears below.

Comment: A few commenters disagreed with our proposal to recoup the difference between the actual list charge and the weighted median private payor rate if the actual list charge is greater than 130 percent of the weighted median private payor rate. The commenters stated that Congress intended to reimburse new ADLTs *up to* 130 percent of the weighted median private payor amount, and the recoupment should serve as a guardrail that prevents abusive laboratory pricing. Additionally, the commenters contended that sound public policy, as well as a natural reading of the statute, dictates that Medicare regard the recoupment provision as an outer boundary limiting the actual list charge. To that end, the commenters requested that CMS recoup the difference *between* the actual list charge and 130 percent of the weighted median private payor rate, rather than the difference between the actual list charge and 100 percent of the weighted median private payor rate.

Other stakeholders stated that our proposed recoupment policy would provide a disincentive for laboratories offering new ADLTs to negotiate price concessions with private payors. For example, they believe that if laboratories performing new ADLTs negotiate price concessions with commercial payors, it will lower the weighted median private payor rate and make it more likely that the ADLT will reach the 130 percent recoupment threshold. Therefore, laboratories offering new ADLTs may refuse to negotiate price concessions with commercial payors to avoid the recoupment threshold.

Response: As discussed in this section, we proposed to recoup the entire amount of the difference between the actual list charge and the weighted median private payor rate if the actual list charge is greater than 130 percent of the weighted median private payor rate. We did so because, while we acknowledged in the proposed rule that the statute could be interpreted to permit the Secretary to recoup the difference between the Medicare payment amount during the initial period and 130 percent of the weighted median rate, we believed that the more straightforward interpretation directed the Secretary to recoup the entire amount. Under our proposed policy, if the difference between actual list charge and the weighted median private payor rate was not greater than 130 percent, the recoupment provision would not apply and the test would be paid at the "actual list charge" during the entire new ADLT initial period.

After review of the public comments, we recognize our proposed policy would create a disparity in the application of recoupment of payments. Under our proposal, if the difference between the actual list charge and the weighted median private payor rate is not greater than 130 percent (for example, if it is exactly 130 percent), then there would be no recoupment, but if the difference between the actual list charge and the weighted median private payor rate is greater than 130 percent (for example, if it is 131 percent), then the entire amount of the difference between actual list charge and the weighted median private payor rate would be recouped.

In section II.D. of this final rule, we indicated that we understand a Medicare coverage determination could be a lengthy process for the types of tests that are likely to qualify as ADLTs and that, consequently, a test may be available on the market and paid by private payors before Medicare covers and pays for it. If a test is available to the public long before a Medicare Part B coverage determination is made and ADLT status is granted, the actual list charge could be significantly higher than the weighted median private payor rate based on applicable information reported during the new ADLT initial period. If the actual list charge is greater than 130 percent of the weighted median private payor rate determined during the new ADLT initial period, under our proposed recoupment policy, we would have recouped the entire difference between the actual list charge and the weighted median private payor rate, in which case the single laboratory that develops, offers and furnishes the ADLT would not have been awarded any special payment status during the new ADLT initial period, as contemplated by the statute. Furthermore, we agree our proposed recoupment policy could have been a disincentive for laboratories and private payors to negotiate price concessions because it could have increased the likelihood that the recoupment threshold would have been met.

For these reasons, we are revising our proposed interpretation of the recoupment provision so that during the new ADLT initial period, new ADLTs will be paid up to 130 percent of their weighted median private payor rate. To determine whether the recoupment provision applies, we will compare the

Medicare payment amount based on actual list charge paid during the new ADLT initial period and the weighted median private payor rate from applicable information reported during the new ADLT initial period. If the actual list charge is greater than 130 percent of the weighted median private payor rate determined during the new ADLT initial period, we will recoup the difference between the actual list charge and 130 percent of the weighted median private payor rate. We are revising payment for new ADLTs at § 414.522(c) to codify this change from the proposed rule.

Additionally, as discussed in section II.D., we revised the definition of new ADLT initial period to mean a period of 3 calendar quarters that begins on the first day of the first full calendar quarter following the later of the date a Medicare Part B coverage determination is made and ADLT status is granted by us. See section II.D. for a discussion of the new ADLT initial period.

5. Payment for Existing ADLTs

Section 1834A(i) of the Act requires the Secretary, for the period of April 1, 2014, through December 31, 2016, to use the methodologies for pricing, coding, and coverage for ADLTs in effect on the day before the enactment of PAMA (April 1, 2014), and provides that those methodologies may include crosswalking or gapfilling. Thus, we explained that section 1834A(i) of the Act authorizes us to use crosswalking and gapfilling to pay for existing ADLTs, that is, those ADLTs that are paid for under the CLFS prior to January 1, 2017. The methodologies in effect on March 31, 2014 were gapfilling and crosswalking. Therefore, we proposed to use crosswalking and gapfilling to establish the payment amounts for existing ADLTs. We proposed to reflect this requirement at § 414.507(h) to state that for ADLTs that are furnished between April 1, 2014 and December 31, 2016, payment is made based on crosswalking or gapfilling methods described in proposed § 414.508(a).

A discussion of the comments we received on payment for existing ADLTs, and our responses to those comments, appears below.

Comment: A few commenters recommended that we use the existing MAC rates for existing ADLTs instead of gapfilling or crosswalking pricing methods.

Response: We disagree with the suggestion to use existing MAC rates for pricing existing ADLTs. We believe the purpose of PAMA is for the CLFS to reflect changes in market prices over time, which would not be accomplished by carrying over a previous payment amount. Therefore, we are finalizing the use of crosswalking and gapfilling methodologies for establishing a payment amount for existing ADLTs.

As we discuss in section II.D. of this final rule, in response to comments, we are moving the implementation date of the private payor rate-based CLFS to January 1, 2018. In conjunction with the revised implementation date, we are also adopting a corresponding change for new ADLTs to reflect that a new ADLT is an ADLT for which payment has not been made under the CLFS prior to January 1, 2018. Therefore, the payment amount for existing ADLTs will be determined based on crosswalking and gapfilling for ADLTs furnished through December 31, 2017, instead of December 31, 2016, which is reflected in revised § 414.507(h).

6. Payment for New CDLTs That Are Not ADLTs

Section 1834A(c) of the Act includes special provisions for determining payment for new CDLTs that are not ADLTs. Section 1834A(c)(1) of the Act states that payment for a CDLT that is assigned a new or substantially revised HCPCS code on or after the April 1, 2014 enactment date of PAMA, which is not an ADLT, will be determined using crosswalking or gapfilling during an initial period until payment rates under section 1834A(b) of the Act are established. The test must either be crosswalked (as described in § 414.508(a) or any successor regulation) to the most appropriate existing test on the CLFS or, if no existing test is comparable, paid according to a gapfilling process that takes into account specific sources of information, which we describe later in this section.

We developed our current procedures for crosswalking and gapfilling new CDLTs pursuant to section 1833(h)(8) of the Act. Section 1833(h)(8)(A) of the Act requires the Secretary to establish by regulation procedures for determining the basis for, and amount of, payment for any CDLT for which a new or substantially revised HCPCS code is assigned on or after January 1, 2005. Section 1833(h)(8)(B) of the Act specifies the annual public consultation process that must take place before the Secretary can determine payment amounts for such tests, and section 1833(h)(8)(C) of the Act requires the Secretary to implement the criteria for making such determinations and make available to the public the data considered in making such determinations. We implemented these provisions in the CY 2007 PFS final rule (71 FR 69701 through 69704) published in the **Federal Register** on December 1, 2006.

We interpreted section 1834A(c) of the Act to generally require us to use the existing procedures we implemented in 42 CFR part 414, subpart G. However, we explained that we needed to make some changes to our current regulations to reflect specific provisions in section 1834A(c) of the Act, as well as other aspects of section 1834A of the Act and the proposed rule. In this section, we describe those proposed changes and how they would affect our current process for setting payment rates for new CDLTs. To incorporate section 1834A of the Act within the basis and scope of payment for CDLTs, we proposed to add a reference to 42 CFR part 414, subpart A, entitled "General Provisions," in § 414.1.

In addition, we proposed to change the title of 42 CFR part 414, subpart G, to reflect that it applies to payment for all CDLTs, not just new CDLTs. We also proposed to add a reference to section 1834A of the Act in § 414.500. To reflect that § 414.500 would apply to a broader scope of laboratory tests than just those covered by section 1833(h)(8) of the Act, we proposed to remove "new" and "with respect to which a new or substantially revised Healthcare Common Procedure Coding System code is assigned on or after January 1, 2005."

a. Definitions

As previously noted, section 1834A(c) of the Act addresses payment for a CDLT that is not an ADLT and that is assigned a new or substantially revised HCPCS code on or after April 1, 2014, PAMA's enactment date. Our current regulations apply throughout to a "new test," which we currently define in § 414.502 as any CDLT for which a new or substantially revised HCPCS code is assigned on or after January 1, 2005. We proposed to replace "new test" with "new CDLT" in § 414.502 and to make conforming changes throughout the regulations to distinguish between the current requirements that apply to new tests and the proposed requirements that would apply to new CDLTs. Our proposed definition specified that a new CDLT means a CDLT that is assigned a new or substantially revised Healthcare Common Procedure Coding System (HCPCS) code, and that does not meet the definition of an ADLT. Section 1834A(c)(1) of the Act uses the same terminology as section 1833(h)(8)(A) of the Act, "new or substantially revised HCPCS code," which we incorporated into the definition of new test in § 414.502. We also defined "substantially revised HCPCS code" in

§ 414.502 based on the statutory definition in section 1833(h)(8)(E)(ii) of the Act to mean a code for which there has been a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test). Because section 1834A(c)(1) of the Act uses terminology that we have already defined, and is consistent with our current process, we did not propose any changes to the phrase "new or substantially revised HCPCS code" in our proposed definition of new CDLT or to the existing definition for "substantially revised HCPCS code."

We did not receive any comments on our proposed payment for new CDLTs that are not ADLTs or the proposed definitions discussed above.

b. Crosswalking and Gapfilling

Background: As we explained in the CY 2008 PFS final rule with comment period (71 FR 66275 through 66276), under current § 414.508, we use one of two bases for payment to establish a payment amount for a new test. Under § 414.508(a), the first basis, called "crosswalking," is used if a new test is determined to be comparable to an existing test, multiple existing test codes, or a portion of an existing test code. If we use crosswalking, we assigned to the new test code the local fee schedule amount and NLA of the existing test code or codes. If we crosswalk to multiple existing test codes, we determine the local fee schedule amount and NLA based on a blend of payment amounts for the existing test codes. Under § 414.508(a)(2), we pay the lesser of the local fee schedule amount or the NLA. The second basis for payment is "gapfilling." Under § 414.508(b), we use gapfilling when no comparable existing test is available. We instruct each MAC to determine a contractor-specific amount for use in the first year the new code is effective. (We note that we proposed to replace "carrier" with "contractor" to reflect that Medicare has replaced fiscal intermediaries and carriers with MACs.) The sources of information MACs examine in determining contractor-specific amounts include:

- Charges for the test and routine discounts to charges;
- Resources required to perform the test;
- Payment amounts determined by other payors; and
- Charges, payment amounts, and resources required for other tests that may be comparable (although not similar enough to justify crosswalking) or otherwise relevant.

During the first year a new test code is paid using the gapfilling method, contractors are required to establish contractor-specific amounts on or before March 31. Contractors may revise their payment amounts, if necessary, on or before September 1, based on additional information. After the first year, the contractor-specific amounts are used to calculate the NLA, which is the median of the contractor-specific amounts, and under § 414.508(b)(2), the test code is paid at the NLA in the second year. We instruct MACs to use the gapfilling method through program instruction, which lists the specific new test code and the timeframes to establish contractor-specific amounts.

In the CY 2007 PFS final rule with comment period (71 FR 69702), we also described the timeframes for determining the amount of and basis for payment for new tests. The codes to be included in the upcoming year's fee schedule (effective January 1) are available as early as May. We list the new clinical laboratory test codes on our Web site, usually in June, along with registration information for the public meeting, which is held no sooner than 30 days after we announce the meeting in the **Federal Register**. The public meeting is typically held in July. In September, we post our proposed determination of the basis for payment for each new code and seek public comment on these proposed determinations. The updated CLFS is prepared in October for release to our contractors during the first week in November so that the updated CLFS is ready to pay claims effective January 1 of the following calendar year. Under § 414.509, for a new test for which a new or substantially revised HCPCS code was assigned on or after January 1, 2008, we accept reconsideration requests in written format for 60 days after making a determination of the basis for payment (either crosswalking or gapfilling) regarding whether we should reconsider the basis for payment and/or amount of payment assigned to the new test. If a requestor recommends that the basis for payment should be changed from gapfilling to crosswalking, the requestor may also recommend the code or codes to which to crosswalk the new test. The reconsideration request would be presented for public comment at the next public meeting, the following year. After considering the public comments, if we decide to change the amount of payment for the code, the new payment amount would be effective January 1 of the year following the reconsideration.

c. Proposal

Section 1834A(c)(1) of the Act refers to payment for CDLTs for which a new or substantially revised HCPCS code is assigned on or after the April 1, 2014 PAMA enactment date. We noted in the proposed rule (80 FR 59410) that the annual crosswalking and gapfilling process had already occurred for codes on the 2015 CLFS, and was currently underway for codes on the 2016 CLFS. We proposed to continue using the current crosswalking and gapfilling processes for CDLTs assigned new or substantially revised HCPCS codes prior to January 1, 2017 because:

- Section 1834A(c)(1)(A) of the Act refers to our existing crosswalking process under § 414.508(a);
- We would not be able to finalize new crosswalking requirements as of PAMA's April 1, 2014 enactment date; and
- The current payment methodology involving NLAs and local fee schedule amounts would remain in effect until January 1, 2017.

We proposed to update § 414.508 by changing the introductory language to limit paragraphs (a) and (b) (which would be redesignated as paragraphs (a)(1) and (2)) to tests assigned new or substantially revised HCPCS codes "between January 1, 2005 and December 31, 2016," and adding introductory language preceding new proposed paragraphs (b)(1) and (2) to reflect our proposal to pay for a CDLT that is assigned a new or substantially revised HCPCS code on or after January 1, 2017 based on either crosswalking or gapfilling.

For CDLTs that are assigned a new or substantially revised HCPCS codes on or after January 1, 2017, we proposed to use comparable crosswalking and gapfilling processes that were modified to reflect the new market-based payment system under section 1834A of the Act. We noted in the proposed rule that, beginning January 1, 2017, the payment methodology established under section 1834A(b) of the Act would replace the current payment methodology under sections 1833(a), (b), and (h) of the Act, including NLAs and local fee schedule amounts. Thus, we proposed to establish § 414.508(b)(1) and (2) to describe crosswalking and gapfilling processes that do not involve NLAs or local fee schedule amounts.

Regarding the crosswalking process, because section 1834A(c)(1)(A) of the Act specifically references our existing process under § 414.508(a), we did not propose to change the circumstances when we use crosswalking, that is, when we determine the new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code. For a CDLT assigned a new or substantially revised HCPCS code on or after January 1, 2017, we proposed to establish the following crosswalking process in § 414.508(b)(1), which does not rely on NLAs or local fee schedule amounts:

d. Crosswalking and Gapfilling

Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code.

- We assign to the new CDLT code, the payment amount established under § 414.507 for the existing test.
- Payment for the new CDLT code is made at the payment amount established under § 414.507 for the existing test.

Regarding the gapfilling process, section 1834A(c)(2) of the Act requires the use of gapfilling if no existing test is comparable to the new test. Section 1834A(c)(2) of the Act specifies that this gapfilling process must take into account the following sources of information to determine gapfill amounts, if available:

- Charges for the test and routine discounts to charges.
- Resources required to perform the test.
- Payment amounts determined by other payors.
- Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.
- Other criteria the Secretary determines appropriate.

The first four criteria are identical to the criteria currently specified in § 414.508(b)(1). For this reason did not propose any substantive changes to the factors that must be considered in the gapfilling process. The fifth criterion authorizes the Secretary to establish other criteria for gapfilling as the Secretary determines appropriate. We did not propose any additional factors to determine gapfill amounts. We noted that, if we decided to establish additional gapfilling criteria, we would do so through notice and comment rulemaking.

We proposed to establish a gapfilling process for CDLTs assigned a new or substantially revised HCPCS code on or after January 1, 2017, that would be similar to the gapfilling process currently included in § 414.508(b), but would eliminate the reference to the NLA in § 414.508(b)(2), as that term would no longer be applicable, and would substitute "Medicare Administrative Contractor" (MAC) for "carrier," as MACs are now Medicare's claims processing contractors. To determine a payment amount under this gapfilling process, we proposed to pay the test code at an amount equal to the median of the contractor-specific payment amounts, consistent with the current gapfilling methodology at § 414.508(b). We proposed § 414.508(b)(2) would state that gapfilling is used when no comparable existing CDLT is available. We proposed in § 414.508(b)(2)(i) that, in the first year, Medicare Administrative Contractor-specific amounts would be established for the new CDLT code using the following sources of information to determine gapfill amounts, if available:

- Charges for the test and routine discounts to charges;
- Resources required to perform the test;
- Payment amounts determined by other payors; and
- Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.
- Other criteria CMS determines appropriate.

We proposed in § 414.508(b)(2)(ii) that, in the second year, the CDLT code would be paid at the median of the MAC-specific amounts.

We noted that section 1834A(c)(1) of the Act requires the crosswalked and gapfilled payment amounts for new CDLTs to be in effect "during an initial period" until payment rates under section 1834A(b) of the Act are established. As discussed, we typically list new CDLT codes on our Web site by June, and by January 1 of the following calendar year, we have either established payment amounts using crosswalking or indicated that a test is in its first year of the gapfilling process. Because we proposed to largely continue our existing gapfilling and crosswalking processes, for CDLTs assigned new or substantially revised HCPCS codes on or after January 1, 2017, we believed the initial period should be the period of time until applicable information is reported for a CDLT and can be used to establish a payment amount using the weighted median methodology in § 414.507(b). We proposed to continue to permit reconsideration of the basis and amount of payment for CDLTs as we currently do under § 414.509. For a new CDLT for which a new or substantially revised HCPCS code was assigned on or after January 1, 2008, we accept reconsideration requests in written format for 60 days after making a determination of the basis for payment (either crosswalking or gapfilling) or the payment amount assigned to the new test code, per § 414.509(a)(1), (b)(1)(i) and (b)(2)(ii). The requestor may also request to present its reconsideration request at the next annual public meeting, typically convened in July of each year under § 414.509(a)(2)(i) and (b)(1)(ii)(A). Under § 414.509(a)(1), if a requestor recommends that the basis for payment should be changed from gapfilling to crosswalking, the requestor may also recommend the code or codes to which to crosswalk the new test. We noted that we might reconsider the basis for payment under § 414.509(a)(3) and (b)(1)(iii) or its determination of the amount of payment, which could include a revised NLA for the new code under § 414.509(b)(2)(v) based on comments. However, as noted in this section, we explained in the proposed rule that the NLA would no longer be applicable on or after January 1, 2017, and we would instead refer to the national payment amount under crosswalking or gapfilling as the median of the contractor-specific payment amounts. Therefore, we proposed to revise § 414.509 to replace references to the "national limitation amount" with "median of the Medicare Administrative Contractor-specific payment amount" in § 414.509(b)(2)(iv) and (b)(2)(v). We also proposed to replace "carrier-specific amount" where it appears in § 414.509 with "Medicare Administrative Contractor-specific payment amount" because we now refer to our Medicare Part B claims processing contractors as Medicare Administrative Contractors.

As we discuss in this final rule, in response to comments, we are moving the implementation date of the private payor rate-based CLFS to January 1, 2018. We believe it is also appropriate for us to adopt corresponding changes to several timeframes we proposed in § 414.508. We are replacing December 31, 2016, with December 31, 2017 in the introductory paragraph of § 414.508(a) to indicate, for a new CDLT that is assigned a new or substantially revised code between January 1, 2005 and December 31, 2017, we determine the payment amount based on either crosswalking or gapfilling, as specified in paragraph (a)(1) or (2). We are also replacing January 1, 2017, with January 1, 2018 in the introductory paragraph of § 414.508(b) to indicate, for a new CDLT that is assigned a new or substantially revised HCPCS code on or after January 1, 2018, we determine the payment amount based on either crosswalking or gapfilling, as specified in paragraph (b)(1) or (2).

A discussion of the comments we received on crosswalking and gapfilling and our responses to those comments appears below.

Comment: One commenter requested that we modify the gapfilling process for establishing a payment amount for CDLTs assigned new or substantially revised HCPCS codes to more accurately account for the resources required to perform a test. To that end, the commenter suggested that laboratories be required to submit "laboratory methods" to the MACs for an assessment of the steps required to perform the new and/or previously unpriced test as part of the requirement that contractors take into consideration the resources required to perform a test when determining a gapfill payment amount.

Response: We appreciate the commenter's suggestions for making revisions to the gapfill methodology. However, we believe our gapfill methodology, revised to reflect section 1834A(c)(2) of the Act, is sufficient for establishing the CLFS payment amount for new CDLTs that are not ADLTs. Under the gapfill criteria, MACs are permitted to take into account laboratory methods, and we trust they will do so if they believe it is necessary. If we determine that additional changes are necessary to establish payment amounts for new CDLTs under the revised CLFS, we may propose modifications to our policies, which we would do through notice and comment rulemaking.

e. Public Consultation Procedures

(1) Advisory Panel Recommendations

Our current procedures for public consultation for payment for a new test are addressed in § 414.506. Section 1834A(c)(3) of the Act requires the Secretary to consider recommendations from the expert outside advisory panel established under section 1834A(f)(1) of the Act when determining payment using crosswalking or gapfilling processes. In this section, we describe the Advisory Panel on CDLTs (the Panel). We proposed to specify that the public consultation process regarding payment for new CDLTs on or after January 1, 2017, must include the Panel's recommendations by adding § 414.506(e) to specify that we will consult with an expert outside advisory panel, called the Advisory Panel on CDLTs, composed of an appropriate selection of individuals with expertise, which may include molecular pathologists, researchers, and individuals with expertise in laboratory science or health economics in issues related to CDLTs . We proposed that this advisory panel would provide input on the establishment of payment rates under § 414.508 and provide recommendations to CMS under this subpart.

A discussion of the comments we received on the Panel is included in section II.J.1. of this final rule.

(2) Explanation of Payment Rates

Section 1834A(c)(4) of the Act requires the Secretary to make available to the public an explanation of the payment rate for a new CDLT, including an explanation of how the gapfilling criteria are applied and how the recommendations of the Advisory Panel on CDLTs are applied. Currently, § 414.506(d) provides that, considering the comments and recommendations (and accompanying data) received at the public meeting, we develop and make available to the public (through a Web site and other appropriate mechanisms) a list of:

- Proposed determinations of the appropriate basis for establishing a payment amount for each code, with an explanation of the reasons for each determination, the data on which the determinations are based, and a request for public written comments within a specified time period on the proposed determinations; and
- Final determinations of the payment amounts for tests, with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions from the public.

Section 414.506(d) already indicates that we will provide an explanation of the payment rate determined for each new CDLT and the rationale for each determination. As described above, under our current process, we make available to the public proposed payment rates with accompanying rationales and supporting data, as well as final payment rates with accompanying rationales and supporting data. However, this process has been used almost exclusively for new tests that are crosswalked. For tests that are gapfilled, we generally post the contractor-specific amounts in the first year of gapfilling on the CMS Web site and provide for a public comment period, but do not typically provide explanations of final payment amounts. Based on section 1834A(c)(4) of the Act, we proposed to amend § 414.506 to explicitly indicate that, for a new CDLT on or after January 1, 2017, we would provide an explanation of gapfilled payment amounts and how we took into account the Panel's recommendations. Specifically, we proposed to add paragraphs (3) and (4) to § 414.506(d). In § 414.506(d)(3), we proposed to specify that, for a new CDLT, in applying paragraphs (d)(1) and (2), we will provide an explanation of how we took into account the recommendations of the Advisory Panel on CDLTs. In § 414.506(d)(4), we proposed to specify that, for a new CDLT, in applying paragraphs (d)(1) and (2) and § 414.509(b)(2)(i) and (iii) when we use the gapfilling method described in § 414.508(b)(2), we will make available to the public an explanation of the payment rate for the test.

Under these provisions, we proposed to publish the Medicare payment amounts for new CDLTs along with an explanation of the payment rate and how the gapfilling criteria and recommendations by the Advisory Panel on CDLTs were applied via the CMS CLFS Web site as we currently do for new tests. The CMS CLFS Web site may be accessed at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/*.

As we discuss in this final rule, we are moving the implementation date of the private payor rate-based CLFS until January 1, 2018. We believe it is also appropriate for us to adopt corresponding changes to several timeframes we proposed in § 414.506. Accordingly, in § 414.506(d)(3) and (4), we are replacing January 1, 2017 with January 1, 2018 to identify our obligations with respect to procedures for public consultation for payment for new CDLTs beginning January 1, 2018.

Comment: We received a few comments supporting our proposal to publish an explanation of payment rates.

Response: We appreciate the commenters' support.

7. Medicare Payment for Tests Where No Applicable Information Is Reported

While sections 1834A(b), (c), and (d), of the Act, respectively, address payment for CDLTs and ADLTs as of January 1, 2017, the statute does not address how we must pay for a laboratory test when no applicable information is reported for applicable laboratories.

There are several possible reasons why no applicable information would be reported for a laboratory test. For example:

- *Test is Not Performed for Any Privately Insured Patients During the Data Collection Period.* One reason we may not receive any applicable information is that the test is not performed for a privately insured patient by an applicable laboratory during the data collection period.

- *Test is Not Performed by Any Applicable Laboratories.* Another reason why we may not receive applicable information is that none of the laboratories performing the test during a data collection period are applicable laboratories as defined in proposed § 414.502. For example, the laboratories could be hospital laboratories that, in a data collection period, did not meet the majority of Medicare revenues threshold or the low expenditure threshold. We estimated that in 2013 there were about 17 laboratory tests with utilization completely attributed to entities that would not have been applicable laboratories because they did not meet the low expenditure threshold.
- *Special Situations Involving ADLTs.* It is also possible that a laboratory that performs a test that would qualify as an ADLT, does not meet the definition of an applicable laboratory and, therefore, no applicable information could be reported for it. As discussed in this section, an ADLT is a test that is performed by only a single laboratory. If that laboratory is not an applicable laboratory, we would not receive applicable information for the test. As discussed above in this final rule, this situation could occur if the only laboratory performing the test did not meet the majority of Medicare revenue threshold or the low expenditure threshold. A discussion of the majority of Medicare revenues threshold and low expenditure threshold is included in section II.A. of this final rule.
- *Other Possible Reasons.* It is possible we may not receive applicable information for a laboratory test if a reporting entity fails to comply with the reporting requirements under section 1834A of the Act, in which case penalties under section 1834A(a)(9) of the Act may be applied. There may also be other reasons we cannot anticipate where we might not receive applicable information for a laboratory test in a data reporting period.

In the event we do not receive applicable information for a laboratory test that is paid under the CLFS, we would need to determine a payment amount for the test in the year following the data collection period. The statute does not specify the methodology we must use to establish the payment rate for an ADLT or CDLT for which we receive no applicable information in a data reporting period but for which we need to establish a payment amount. In such circumstances, we proposed to use crosswalking and gapfilling using the requirements we proposed for those methodologies in § 414.508(b)(1) and (2) to establish a payment rate on or after January 1, 2017 (which will now be January 1, 2018, in accordance with the change to the implementation date of the revised CLFS), which would remain in effect until the year following the next data reporting period. We proposed this policy would include the situation where we receive no applicable information for tests that were previously priced using gapfilling or crosswalking or where we had previously priced a test using the weighted median methodology. If we receive no applicable information in a subsequent data reporting period, we propose to use crosswalking or gapfilling methodologies to establish the payment amount for the test. That is, if in a subsequent data reporting period, no applicable information is reported, we would reevaluate the basis for payment, —crosswalking or gapfilling— and the payment amount for the test.

In exploring what we would do if we receive no applicable information for a CDLT, we alternatively considered carrying over the current payment amount for a test under the current CLFS, the payment amount for a test (if one was available) using the weighted median methodology based on applicable information from the previous data reporting period, or the gapfilled or crosswalked payment amount. However, we did not propose this approach because we believed carrying over previous payment rates would not reflect changes in costs or pricing for the test over time. We understood the purpose of section 1834A of the Act to be update the CLFS rates to reflect changes in market prices over time.

As noted above, the statute does not address situations where we price a test using crosswalking or gapfilling because we received no applicable information with which to determine a CLFS rate. We believed reconsidering rates for tests in these situations would be consistent with the purpose of section 1834A of the Act, which requires us to periodically reconsider CLFS payment rates. In the case of tests for which we previously received applicable information to determine payment rates, section 1834A of the Act requires Medicare to follow changes in the market rates for private payors. Our proposal served an analogous purpose by having us periodically reconsider the payment rate of a test using gapfilling or crosswalking. We stated in the proposed rule that we expected to continue to evaluate our proposed approach to setting rates for laboratory tests paid on the CLFS with no reported applicable information as we gained more programmatic experience under the new CLFS. We indicated that any revisions to how we determine a rate for laboratory tests without reported applicable information would be addressed in the future through notice and comment rulemaking.

In summary, we proposed that for a CDLT, including ADLTs, for which we receive no applicable information in a data reporting period, we would determine the payment amount based on either crosswalking or gapfilling. We proposed to add paragraph (g) to § 414.507 to specify that for CDLTs for which we receive no applicable information, payment would be made based on the crosswalking or gapfilling methods described in § 414.508(b)(1) and (2).

A discussion of the comments we received on Medicare payment for tests where no applicable information is reported, and our responses to those comments, appears below.

Comment: A few commenters suggested that we carry over prices for any tests for which we receive no private payor data during a data reporting period. They contended that simply carrying over the payment amount established for the previous update would be a more logical approach than reevaluating the payment basis (crosswalk versus gapfill) for a test for which payment had once been established.

Response: As discussed previously, we considered carrying over the current payment amount for a test in the event we do not receive any applicable information for a test in a given data reporting period. However, we are not adopting that approach because we understand the purpose of the revised CLFS payment methodology is to update the CLFS rates to reflect changes in market prices over time, and we believe carrying over previous payment rates would not reflect changes in costs or pricing for the test over time.

As we discussed previously, because we are moving the implementation date of the private payor rate-based CLFS to January 1, 2018, we are also adopting a corresponding change to the use of crosswalking and gapfilling methodologies for tests where no applicable information is reported. That is, we are revising § 414.508(a) to reflect that we will use the crosswalking and gapfilling methodologies specified in that section to establish payment rates before January 1, 2018, and we are revising § 414.508(b) to reflect that we will use the crosswalking and gapfilling methodologies specified under § 414.508(b) to establish payment rates beginning January 1, 2018.

In summary, we are revising our proposed policy for recouping payment for new ADLTs if the actual list charge paid during the new ADLT initial period exceeds 130 percent of the market-based rate as discussed above in this section. If the actual list charge is greater than 130 percent of the weighted median private payor rate determined during the new ADLT initial period, we will recoup the difference between the actual list charge and 130 percent of the weighted median private payor rate. We are also making changes corresponding to the January 1, 2018 implementation date of the private payor rate-based CLFS as discussed in this section. We are finalizing all other payment methodology policies in this section as proposed.

I. Local Coverage Determination Process and Designation of Medicare Administrative Contractors for Clinical Diagnostic Laboratory Tests

Section 1834A(g) of the Act addresses issues related to coverage of CDLTs. Section 1834A(g)(1)(A) of the Act requires that coverage policies for CDLTs, when issued by a MAC, be issued in accordance with the LCD process. The current LCD development and implementation process is set forth in agency guidance. Section 1869(f)(2)(B) of the Act defines an LCD as a determination by a MAC under part A or part B, as applicable, respecting whether or not a particular item or service is covered on a MAC jurisdiction-wide basis under such parts, in accordance with section 1862(a)(1)(A) of the Act.

While the LCD development process is not enumerated in statute, CMS' Internet-Only Manual 100–08, Medicare Program Integrity Manual, Chapter 13, lays out the process for establishing LCDs. The manual outlines the steps in LCD development including: The posting of a draft LCD with a public comment period, a public meeting and presentation to an expert advisory committee, and, after consideration of comments, issuance of a final LCD followed by at least a 45-day notice period prior to the policy becoming effective. This LCD development process has been used by the MACs since 2003.

In addition to addressing LCD development and implementation, section 1834A(g)(1)(A) of the Act states that the processes governing the appeal and review of LCDs for CDLTs must be consistent with the general LCD appeal and review rules that we have issued at 42 CFR part 426. The LCD appeals process allows an "aggrieved party" to challenge an LCD or LCD provisions in effect at the time of the challenge. An aggrieved party is defined as a Medicare beneficiary, or the estate of a Medicare beneficiary, who is entitled to benefits under Part A, enrolled under Part B, or both (including an individual enrolled in fee-for-service Medicare, in a Medicare+Choice plan, or in another Medicare managed care plan), and is in need of coverage for an item or service that would be denied by an LCD, as documented by the beneficiary's treating physician, regardless of whether the service has been received.

Section 1834A(g)(1)(B) of the Act provides that the CDLT-related LCD provisions referenced in section 1834A(g) do not apply to the NCD process (as defined in section 1869(f)(1)(B) of the Act). The NCD process is outlined in section 1862(l) of the Act and further articulated in the August 7, 2013 **Federal Register** (78 FR 48164).

Section 1834A(g)(1)(C) of the Act specifies that the provisions pertaining to the LCD process for CDLTs, including appeals, shall apply to coverage policies issued on or after January 1, 2015.

Beyond specifying how the Medicare LCD process will relate to CDLTs, section 1834A(g)(2) of the Act provides the Secretary the discretion to designate one or more (not to exceed four) MACs to either establish LCDs for CDLTs or to both establish LCDs and process Medicare claims for payment for CDLTs. Currently, there are 12 MACs that have authority to establish LCDs and process claims for CDLTs. We believe the statute authorizes us to reduce the number of MACs issuing LCDs for CDLTs, which would result in fewer contractors issuing policies for larger geographic areas. If we were to exercise only the authority to reduce the number of MACs issuing LCDs for CDLTs, such a change could likely be finalized within the next 2 to 4 years. However, reducing the number of MACs processing claims for CDLTs would involve significantly more complex programmatic and operational issues. For instance, the consolidation of Medicare claims processing for CDLTs would require complex changes to Medicare's computer systems. Thus, such a transition could take several years to implement. To be consistent with the statute, we believe the agency would need to conduct various analyses to determine the feasibility and program desirability of moving forward with consolidating the number of MACs making coverage policies and processing claims for CDLTs. We believe that the medical complexity of many tests and the volume of tests overall would require serious consideration of several factors before the agency could decide whether to consolidate all MAC CDLT processes into 1–4 MACs. For instance, if only coverage policies were to be developed by a smaller number of MACs, issues could arise for the other MACs that would need to implement policies, edit claims and defend LCD policies that they did not author. Moreover, the same policy may be implemented differently among MACs based on the ability of their individual claims processing systems to support certain types of editing and/or their differing assessment of risk and technical solutions. Finally, if both LCD development and claims processing were combined and consolidated, we would need to consider that the MAC processing the laboratory claim (in most cases) would not be the same MAC that processes the claim of the ordering physician. This could complicate the development of a full profile of the ordering physician's practice patterns for quality and medical necessity assessment purposes.

The timing for implementation of section 1834A(g)(2) of the Act (if we chose to exercise this authority) would be largely dependent on the time it would take the agency to develop new MAC statements of work, modify existing or develop new MAC contracts, and address the policy, information technology and technical aspects of the claims processing environment including the potential development of a new system. Implementing the fullest scope of the authority granted by this section, by which we would reduce both the number of MACs writing coverage policies for CDLT services and the number of MACs processing CDLT claims, could take at least 5 to 6 years and involve considerable costs. For example, to establish centralized LCDs for all CDLTs would probably involve an initial build-up and then a steady-state investment of several million dollars per year. To create regional lab test claims processors (in addition to development of LCDs) would involve higher set-up costs, and some steady-state costs.

We received 27 comments on these proposals. Of those comments, two commenters were in favor of consolidating both LCD development and claims processing for CDLTs. Five commenters were in favor of only MAC LCD consolidation for CDLTs. Of those five comments, four commenters said we may want to consider having MACs consolidate their LCDs for CDLTs but also raised concerns about such consolidation. Seven commenters were not in favor of having the MACs consolidate their LCDs for CDLTs. In regard to designating 1–4 MACs to process CDLT claims, 3 commenters were in favor and 11 commenters were not in favor of consolidating claims processing for CDLTs.

A discussion of the comments we received on the benefits and risks of implementing the various scenarios authorized by this section of the statute, and our response to those comments, appears below.

a. Claims Processing Consolidation

Comments: Several commenters stated that they believe working with a single MAC to process all claims was preferred because of the increased paperwork and reporting burden associated with submitting claims to more than one MAC. These same commenters stated that the disadvantages of having a MAC process only CDLT claims would far outweigh the benefits; therefore, they were strongly opposed to designating more than one MAC to conduct claims processing.

Two commenters indicated that consolidating claims processing functions under 1–4 MACs may be problematic unless consolidation of claims processing functions applies only to independent labs. One commenter offered an alternative of using the Master Edit File to address CMS' concerns about the complexities of consolidating CDLT claims processing. This file, designed to function similarly to the Part B Drug Crosswalk Pricing file and the National Correct Coding Initiative edit file, could standardize processing across the MACs. Tools such as the Integrated Data Repository could also facilitate the necessary data analysis and payment review processes being performed at a single contractor.

b. LCD Consolidation

Comments: Several commenters recommended that CMS move to a system that consolidates the MACs for the purpose of administering coverage determinations for laboratory tests. The commenters varied on the total number of MACs CMS should use for CDLT coverage policies.

Two commenters indicated that CMS should consider designating a single contractor. One of these commenters believes a single contractor should be designated that has expertise in laboratory and precision medicine with the responsibility for coverage determinations for such tests. The commenter believes it would be difficult as well as inefficient for each MAC to develop this substantial and specialized expertise in laboratory medicine. The other commenter disagreed that it would take years to implement a national LCD process, and provided some suggestions on the LCD development process so that all MACs could release CDLT LCDs at the same time.

Four commenters indicated that if CMS were to move forward with fewer MACs developing LCDs it may put some MACs in a position of having to defend and/or abide by LCDs they did not develop. This could also create regional differences in how the same LCD would be enforced because a MAC's claims processing systems and editing capabilities differ.

Response: We appreciate the thoughtful comments on whether CMS should consolidate the MACs for the purpose of developing coverage policies and processing claims for CDLTs. Careful consideration will be given to the input from stakeholders as we consider whether to downsize the number of MACs developing LCDs and/or processing claims for CDLTs. In the interim, MACs should continue to develop and implement CDLT-related LCDs in accordance with the guidance set forth in Chapter 13 of the Medicare Program Integrity Manual and process Medicare claims for payment of CDLTs in the same manner it always has until further notice.

J. Other Provisions

1. Advisory Panel on Clinical Diagnostic Laboratory Tests

Section 1834A(f) of the Act sets out several requirements for input from clinicians and technical experts on issues related to CDLTs. Section 1834A(f)(1) of the Act requires the Secretary to consult with an expert outside advisory panel that is to be established by the Secretary no later than July 1, 2015. This advisory panel must be composed of an appropriate selection of individuals with expertise, which may include molecular pathologists, researchers, and individuals with expertise in laboratory science or health economics, in issues related to CDLTs, which may include the development, validation, performance, and application of such tests.

Section 1834A(f)(1)(A) of the Act provides that the advisory panel will generally provide input on the establishment of payment rates for new CDLTs, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test and the factors used in determining coverage and payment processes for new CDLTs. Section 1834A(f)(1)(B) of the Act provides that the panel will provide recommendations to the Secretary under section 1834A of the Act. Section 1834A(f)(2) of the Act mandates that the panel comply with the requirements of the Federal Advisory Committee Act (5 U.S.C. App.) (FACA). We proposed to add § 414.506(e) to codify the establishment of the Advisory Panel on CDLTs.

In the October 27, 2014 **Federal Register** (79 FR 63919), we announced the Advisory Panel on CDLTs. On April 16, 2015, we established the charter for the Panel. (See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/PAMA-Tab-F-1635-N.pdf*). As indicated in the charter, meetings will be held up to 4 times a year. Meetings will be open to the public except as determined otherwise by the Secretary or other official to whom the authority has been delegated in accordance with the Government in the Sunshine Act of 1976 (5 U.S.C. 552b(c)) and FACA. Notice of all meetings will be published in the **Federal Register** as required by applicable laws and Departmental regulations. Meetings will be conducted, and records of the proceedings kept, as required by applicable laws and departmental regulations. Additionally, in the August 7, 2015 **Federal Register** (80 FR 47491), we announced membership appointments to the Panel along with the first meeting date for the Panel. As we do with the Advisory Panel on Hospital Outpatient Payment (see *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html*), we will make the Advisory Panel on CDLT's recommendations publicly available on the CMS Web site shortly after the panel's meeting. The first meeting of the panel was held at CMS on August 26, 2015. Information regarding the Panel is available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html*.

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: Many commenters appreciated that Congress required the Secretary to establish the Advisory Panel to provide input on the many important issues related to clinical diagnostic laboratory testing and rate setting, and encouraged CMS to make use of the expertise on the Advisory Panel prior to setting payment rates and implementing the final rule.

In addition, a commenter noted that much of the discussion during the

Advisory Panel's meetings on August 26, 2015, and October 19, 2015, focused on specific codes that are being considered for payment on the CLFS in CY 2016, and suggested that the Advisory Panel be used to provide clinical and technical expertise on a wide range of clinical laboratory tests.

Response: We thank the commenters for their support of the Advisory Panel. We agree the Advisory Panel provides valuable expertise and we intend to utilize its input to the extent possible.

Comment: Several commenters suggested that subject matter experts be invited to participate on the Advisory Panel to discuss sub-specialty issues when the Advisory Panel lacks a subject matter expert on a specific issue being discussed.

Response: We appreciate the suggestion and will take it into consideration for future meetings.

Comment: A commenter requested that CMS follow more closely the recommendations of the Advisory Panel so that CMS actively engages in an open, transparent, and public decision-making process.

Response: We agree that the decision-making process should be as open and transparent as possible, and we will continue to consider all recommendations of the Advisory Panel in the decision-making process. We note that the Advisory Panel's meetings are open to the public in accordance with FACA requirements, and information related to the Advisory Panel (agenda, recommendations, etc.) are posted on the CMS Web site at ***https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.***

Comment: Some commenters requested a mechanism for stakeholders to request that specific topics be added to the Advisory Panel's agenda in advance of scheduled meetings.

Response: Stakeholders who wish to request that an item be added to the Advisory Panel's meeting agenda should email their request to *CDLTPanel@cms.hhs.gov.*

Comment: Some commenters recommended adding Advisory Panel members from community-based laboratories to ensure that panel members understand how community-based clinical laboratories operate and the costs associated with providing testing services in a diversity of settings. Other commenters recommended adding panelists that run clinical laboratories, or have recent direct experience in the clinical laboratory industry and knowledge of how policies can be operationalized by clinical laboratories. Another commenter urged CMS to utilize the Advisory Panel to augment the subject matter expertise of MACs on coverage matters.

Response: We appreciate the suggestions and will consider these recommendations when a position on the Advisory Panel becomes available. The 15 Advisory Panel members have extensive expertise in issues related to clinical diagnostic laboratory tests and include representatives of clinical laboratories, molecular pathologists, clinical laboratory researchers, and individuals with expertise in clinical laboratory science or economics of clinical laboratory services. All Advisory Panel members have direct personal experience with clinical laboratory tests and services, and were selected to serve a 3-year term based on their leadership credentials, quality of their clinical laboratory experience, geographic and demographic factors, and the projected needs of the Advisory Panel.

Comment: Some commenters stated that although FACA requires only 15 days advance notice of meetings, CMS should provide at least 30 days notice to allow medical professionals time to plan travel and adjust their schedules to attend. Commenters also requested that CMS explore options to allow public comment via teleconference or webinar so stakeholders could actively participate in the process to address scheduling and cost issues associated with in-person attendance.

Response: We understand that 15 days as required by FACA may not be adequate time for all interested persons to make scheduling and travel arrangements to attend an Advisory Panel meeting. We will strive to provide additional notice whenever possible. Participants are able to call in and live stream the Advisory Panel meetings and we will consider allowing public comments to be provided via these mechanisms as well.

2. Exemption From Administrative and Judicial Review

Section 1834A(h)(1) of the Act states there shall be no administrative or judicial review under sections 1869 and 1878 of the Act, or otherwise, of the establishment of payment amounts under section 1834A of the Act. We proposed to codify this provision in § 414.507(e).

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: Several commenters stated that there are likely to be errors in the data submitted, especially in the initial data reporting period, and since there is no opportunity for administrative or judicial review, they believe rates may be set for a three-year period based on incorrect information. While acknowledging that the law precludes administrative and judicial review of payment amounts, the commenters requested that CMS establish a process to accept requests for review of proposed rates, and noted that this is done in the Physician Fee Schedule and the Hospital Outpatient Prospective Payment System.

Response: We understand there are concerns regarding the accuracy of the data submitted, particularly for the initial data reporting period. As discussed in section II.F of this final rule, we plan to establish a process for public review of the CLFS rates, that is, the weighted median private payor rates, before they are finalized. We intend to make available to the public a list of test codes and the CLFS rates associated with those codes, which is the same CLFS information we currently make available to the public. We stated that, while we will not release any information that identifies a payor or a laboratory, we will also make available to the public a file that includes aggregate-level private payor rate and volume data for each test code (for example, the unweighted median private payor rate; the total, median and or mean volume; number of laboratories reporting), and that this information will be released to the public before the final rates are published to better enable the public to comment about the general accuracy of the reported data. We also noted that we are exploring whether we can make available the raw data that is reported to us (that is, is the actual, un-aggregated data that is reported as applicable information for an applicable laboratory) in order to provide even more granular data for the public's review, but we would not provide aggregate or raw data for tests we consider to be uncommon or that we know to be provided by a single laboratory (such as for new ADLTs) to avoid potential disclosure of the prices charged or payments made to an individual laboratory. We believe this process could provide even more transparency for the public to review and comment on the new CLFS payment rates before they are made effective. Details of this process, if established, will be provided in subregulatory guidance.

3. Sample Collection Fee

Section 1834A(b)(5) of the Act increases by $2 the nominal fee that would otherwise apply under section 1833(h)(3)(A) of the Act for a sample collected from an individual in a SNF or by a laboratory on behalf of a HHA. We stated in the proposed rule that this provision was implemented via Medicare Change Request (CR) transmittal effective December 1, 2014 (Transmittal #R3056CP; CR #8837) and that we proposed to reflect this policy in § 414.507(f). However, Transmittal #R3056CP; CR #8837 was effective April 1, 2014 and implemented December 1, 2014. Therefore, we are revising § 414.507(f) to reflect the effective date for this provision of April 1, 2014.

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: Some commenters believed that our interpretation of the statute has prevented laboratories from receiving the sample collection fee increase if they provide services to patients designated by physicians as homebound, or if they provide services to patients that go back and forth within a shared SNF/NF facility. They noted that we allow HHAs to collect the fee but not to bill Part B for the specimen collection, even though SNFs are allowed to bill Part B for the specimen collection fees. The commenters proposed that we allow laboratories that provide specimen collection services to receive the increase in the fee by billing using place of service codes for SNFs, NFs, and for homebound patients in a private residence.

Response: The statute states that the sample collection fee shall be increased for samples collected from an individual in a SNF or by a laboratory on behalf of a HHA. The authority does not extend to sample specimens collected from patients designated as homebound, even if place of service codes were utilized.

III. Collection of Information Requirements

As stated in section 1834A(h)(2) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the information collection requirements contained in section 1834A of the Act. Consequently, the information collection requirements contained in this final rule need not be reviewed by the Office of Management and Budget.

IV. Waiver of Proposed Notice and Comment Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA). The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. However, this procedure can be waived if the Secretary finds, for good cause, that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefor in the rule.

We are finalizing the CMP amounts adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. 114–74) (the 2015 Act) without public notice and comment. The 2015 Act is very prescriptive in the formula that we must apply in adjusting the civil monetary penalties, leaving us no flexibility to exercise discretion in calculating the inflation adjustments to the CMP amounts. Therefore, we find good cause to waive notice and comment procedures as unnecessary.

V. Regulatory Impact Analysis

A. Statement of Need

This final rule is necessary to establish a methodology for implementing the requirements in section 1834A of the Act, including a process for data collection and reporting, a weighted median calculation methodology, and requirements for how and to whom these policies would apply.

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This final rule is an economically significant rule because we believe that the changes to how CLFS payment rates will be developed will overall decrease payments to entities paid under the CLFS. We estimate that this final rule is "economically significant" as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that, to the best of our ability, presents the costs and benefits of the rulemaking.

C. Limitations of Our Analysis

Our analysis presents the projected effects of our implementation of new section 1834A of the Act. As described earlier in this final rule, a part of this rule describes a schedule and process for collecting the private payor rate information of certain laboratories. Until such time that these data are available, we are limited in our ability to estimate effects of our CLFS payment policies under different scenarios.

D. Anticipated Effects

1. Effects on Entities Paid Under the CLFS

The RFA requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most of the entities paid under the CLFS are small entities as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year).

For purposes of the RFA, we estimate that most entities furnishing laboratory tests paid under the CLFS are considered small businesses according to the Small Business Administration's size standards with total revenues of $32.5 million or less in any 1 year: $32.5 million for medical laboratories and $11 million for doctors. Individuals and states are not included in the definition of a small entity. Using the codes for laboratories in the North American Industry Classification System (NAICS), more than 90 percent of medical laboratories would be considered small businesses. This final rule will have a significant impact on a substantial number of small businesses or other small entities even with an exception for low expenditure laboratories.

In the proposed rule (80 FR 59391through 59394), we proposed to define applicable laboratory at the TIN level. Approximately 68,000 unique TIN entities are enrolled in the Medicare program as a laboratory and paid under the CLFS. Of these unique TIN entities, 94 percent are enrolled as a physician office laboratory, 3 percent are enrolled as independent laboratories while the remaining 3 percent are attributed to other types of laboratories such as those operating within a rural health clinic or a skilled nursing facility. In section II.A. of this final rule, we discussed that after considering commenters' suggestions, we have revised the proposal and, as a final policy, we are defining applicable laboratory at the NPI level. Approximately 266,000 unique NPI-level entities are enrolled in the Medicare program as a laboratory and paid under the CLFS. Of these unique NPI-level entities, 93 percent are enrolled as a physician office laboratory, 1 percent are enrolled as independent laboratories while the remaining 6 percent are attributed to other types of laboratories such as those operating within a rural health clinic or a skilled nursing facility. Given that well over 90 percent of Medicare enrolled laboratories paid under the CLFS are physician-owned laboratories, we estimate the majority of Medicare-enrolled laboratories would meet the SBA definition of a small business. While the NPI-level entity will be the applicable laboratory, the TIN-level entity will be responsible for reporting applicable information for all the NPIs in its organization that are applicable laboratories. We believe that reporting at the TIN level will require reporting from fewer entities and will, therefore, be less burdensome to all types of applicable laboratories—that is independent laboratories, physician office laboratories, and hospital outreach laboratories—than would requiring applicable laboratories to report.

As discussed in section II.B of this final rule, the applicable information required to be reported to CMS includes each private payor rate, the associated volume of tests performed corresponding to each private payor rate, and the specific HCPCS code associated with the test. We specifically intended to minimize the reporting burden by only requiring the minimum information necessary to enable us to set CLFS payment rates. We are not requiring (or permitting) individual claims to be reported because claims include more information than we need to set payment rates (and also raises concerns about reporting personally identifiable information). We believe that each of these policies, which are finalized in this rule, will substantially reduce the reporting burden for reporting entities in general and small businesses in particular.

Given that we have never collected information about private payor rates for tests from laboratories, we do not have the specific payment amounts from the weighted median of private payor rates that will result from implementation of section 1834A of the Act. For this reason, it is not possible to determine an impact at the level of the individual laboratory or physician office laboratory much less distinctly for small and other businesses. While the information provided elsewhere in this impact statement provide the aggregate level of changes in payments, these estimates were done by comparing the differences in payment amounts for laboratory tests from private payers with the Medicare CLFS payment adjusted for changes expected to occur by CY 2018. While this methodology can be used to estimate an overall aggregate change in payment for services paid using the CLFS, the impact on any individual laboratory will depend on the mix of laboratory services provided by the individual laboratory or physician office.

A final regulation is generally deemed to have a significant impact on small businesses if the rule is estimated to have an impact greater than a 3 to 4 percentage change to their revenue. As discussed previously in this section, we estimate that most entities furnishing laboratory tests paid under the CLFS would be considered a small business. Therefore, we believe our accounting statement provides a reasonable representation of the impact of the changes to the CLFS on small businesses (see Table 14). As illustrated in Table 14, the effect on the Medicare program is expected to be $390 million less in Part B program payments for CLFS tests furnished in FY 2018. The 5-year impact is estimated to be $1.71 billion less and the 10-year impact is expected to result in $3.93 billion less in program payments. As discussed previously, overall, Medicare pays approximately $7 billion a year under the current CLFS for CDLTs. Using our estimated amount of changes in CLFS spending, we estimate an overall percentage reduction in revenue of approximately −5.6 percent for FY 2018 (−$390 million/$7 billion = −5.6 percent); a 5-year percentage reduction of about 4.9 percent (−$1.71 billion/$35 billion = −4.9 percent) and a 10-year percentage reduction of approximately 5.6 percent (−$3.93 billion/$70 billion = −5.61percent). As such, we estimate that the revisions to the CLFS as authorized by PAMA will have a significant impact on small businesses.

We note that the above estimates differ from the estimates indicated in the regulatory impact analysis section of the proposed rule. The difference is due to the move in implementation from January 1, 2017, to January 1, 2018. The move not only eliminated a year of potential savings but resulted in less future savings as another year of productivity adjustments will take effect and essentially narrow the gap between private payor rates and Medicare rates.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule will not have a significant impact on small rural hospitals because the majority of entities paid under the CLFS and affected by the policies are independent laboratories and physician offices. To the extent that rural hospitals own independent laboratories and to the extent that rural hospitals are paid under the CLFS, there could be a significant impact on those facilities. Since most payments for laboratory tests to hospitals are bundled in Medicare Severity Diagnosis Related Group payments under Part A, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals. We requested comment from small rural hospitals on (1) their relationships with independent clinical laboratories and (2) the potential impact of a reduction in CLFS payments on their revenues and profits. We received no comments.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that is approximately $146 million. This final rule does not contain mandates that will impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have examined the CLFS provisions included in this final rule in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on state, local or tribal governments, preempt state law, or otherwise have a Federalism implication. While we have limited information about entities billing the CLFS with government ownership, the limited amount of information we currently have indicates that the number of those entities, as well as CLFS payment amounts associated with them, are minimal. Based on 2013 claims data, we received only 21,627 claims for CLFS services from a total of 50 state or local public health clinics (0.1 percent of total laboratories that billed under the CLFS). However, we note that this final rule will potentially affect payments to a substantial number of laboratory test suppliers, and some effects may be significant.

2. Effects on the Medicare and Medicaid Programs

Section 1834A of the Acts requires that the payment amount for tests on the CLFS, beginning January 1, 2017, be based on private payor rates. As discussed in the proposed rule (80 FR 59416), we estimated the effect on the Medicare program is expected to be $360 million less in program payments for CLFS tests furnished in FY 2017. However, as discussed in section II.D of this final rule, we are moving the implementation date of the private payor rate-based CLFS to January 1, 2018. As a result, we revised the estimated amount of change in CLFS spending to reflect the revised implementation date.

The effect on the Medicare program is expected to be $390 million less in program payments for CLFS tests furnished in FY 2018. We first established a baseline difference between Medicare CLFS payment rates and private payor rates based on a study by the Office of Inspector General, "Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings", OEI–07–11–00010, June 2013. The OIG study showed that Medicare paid between 18 and 30 percent more than other insurers for 20 high-volume and/or high-expenditure lab tests. We assumed the private payor rates to be approximately 20 percent lower than the Medicare CLFS payment rates for all tests paid under the CLFS in CY2010. We then accounted for the legislated 5 years of 1.75 percent cuts to laboratory payments, as required by section 1833(h)(2)(A)(iv)(II) of the Act, as well as 8 years of multi-factor productivity adjustments, as required by section 1833(h)(2)(A) of the Act, to establish a new baseline difference between private payor rates and Medicare CLFS payment rates of approximately 5.8 percent in 2018. The new baseline difference between Medicare CLFS payment rates and private payor rates (5.8 percent) results in an approximate savings to the Medicare program of $390 million in FY 2018. We projected the FY 2018 Medicare savings of $390 million forward by assuming a rate of growth proportional to the growth in the CLFS (that is approximately 8.2 percent annually over the projection window FY 2016 through FY 2025) after adjusting for additional productivity adjustments to determine a 10-year cost savings estimate (as illustrated in Table 14). We note that the 1-year move in implementation of this final rule reduces the 10-year estimated amount of change in CLFS spending by approximately $790 million. The effect on the Medicaid program is expected to be limited to payments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We note that section 6300.2 of the CMS State Medicaid Manual states that Medicaid reimbursement for CDLTs may not exceed the amount that Medicare recognizes for such tests.

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: One commenter expressed concern that projected payment reductions for laboratories in 2017 and potential savings for Medicare surpasses the original goals for PAMA. For example, this commenter indicated that CMS projected the new laboratory payment rates to result in $360 million in payment reductions for laboratories in 2017 and potential savings for Medicare of over $5.14 billion over 10 years. The commenter believes these saving estimates are much greater than those released by the Congressional Budget Office (CBO) when PAMA was enacted. The commenters cite that CBO estimated savings of $100 million in 2017 and $2.5 billion over 10 years. The commenter recommended CMS make significant revisions before finalizing the proposed rule.

Response: We acknowledge a difference in payment projections released by CBO and CMS. We believe this difference is due to the following: (1) CBO estimates were based on an OIG[3] study that examined the top 25 Medicare laboratory test payments, whereas our estimates were based on all laboratory tests billed under the CLFS; (2) CBO estimates utilized 2014 Medicare claims data, whereas we used the 2010 OIG data analysis to establish a baseline difference in the payments between CLFS and the private payor rates; and (3) CBO provided payment projections from 2014 to 2024, whereas we provided payment projections from 2016 to 2025.

3. Cost of Data Collection and Reporting Activities

As discussed previously, the applicable information of applicable laboratories must be collected, and reporting entities will be required to report that information to CMS. Section II.E.1. addresses penalties for non-reporting. We believe there could be substantial costs associated with compliance with section 1834A. As we had only limited information upon which to develop a cost estimate for collecting and reporting applicable information, we did not propose an estimate of the cost of data collection and reporting. As discussed below, we provided an illustrative example of the potential magnitude of collecting and reporting applicable information under the revised private payor rate based CLFS.

As noted previously, the CLFS has grown from approximately 400 tests to over 1,300 tests. For the proposed rule, we were not able to ascertain how many private payors and private payor rates there are for each applicable laboratory, and therefore, provided a hypothetical example to illustrate the number of records (with one record being the specific HCPCS code, the associated private payor rate, and volume) that a reporting entity could be required to report for an applicable laboratory under the proposed rule. If an applicable laboratory had 30 different private payor rates for a given test and it received private payor payment for each test on the CLFS, the reporting entity would be reporting 39,000 records (1,300 tests × 30) and 117,000 data points (one data point each for the HCPCS code and its associated private payor rate and volume). We explained that this example is hypothetical and illustrative only but demonstrates the potential volume of information a reporting entity may be required to report for a given applicable laboratory. It seems likely that most applicable laboratories will not have private payor rates for each test on the CLFS and that a small number of tests will have the highest volume and more associated private payor rates. To the extent that a laboratory receives private payor payment for fewer than the 1,300 tests paid under the CLFS, the data collection and reporting burden will be less (and accordingly the 1,300 multiplier will be less) than in the above example. To the extent a private payor has more or less than 30 private payor rates, the multiplier will differ from 30 in the above example.

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[3] HHS OIG Data Brief, Medicare Payment for Clinical Laboratory Tests in 2014: Baseline Data. *Office of Inspector General,* September 2015.

To better understand the projected reporting, recordkeeping or other compliance requirements, we specifically requested comments on the following questions concerning applicable laboratories:

- How many tests on the CLFS does the applicable laboratory perform?
- For each test, how many different private payor rates does the applicable laboratory have in a given period (for example, calendar year or other 12 month reporting period)?
- Does the applicable laboratory receive more than one rate from a private payor in a given period (for example, calendar year or other 12 month reporting period)?
- Is the information that laboratories are required to report readily available in the applicable laboratories' record systems?
- How much time does the applicable laboratory expect will be required to assemble and report applicable information?
- What kind of personnel will the applicable laboratory be using to report applicable information?
- What is the salary per hour for these staff?
- Is there other information not requested in the above questions that will inform the potential reporting burden being imposed by section 1834A of the Act?

We believed that these items would be important factors to consider before projecting data reporting and recordkeeping requirements. A discussion of the comments we received on this topic and our responses to those comment, appears below.

Comment: We received two comments on these items. One commenter expressed concern regarding the impact of anticipated administration burden. For example, the commenter indicated that they would need to make changes to information technology (IT) systems in order to collect, validate and report applicable data to CMS. Another commenter indicated that data reporting provisions in the proposed rule would require significant IT systems changes that could cost $300,000–$600,000. Additionally, the commenter estimated that a manual payment remittance process would cost $1.2 million for a 6 month data collection period and would require hiring 5 full-time equivalent staff at approximately $80,000 in annual salaries, wages and benefits.

Response: As noted above, the CLFS has grown from approximately 400 tests to over 1,300 tests. We assume that none of these tests are only furnished to Medicare beneficiaries or are only charged to Medicare, therefore, we expect applicable information (that is, private payor rates and associated volume) to be reported by applicable laboratories on nearly all of these tests. As discussed in the RIA, approximately 266,000 unique NPI-level entities are enrolled in the Medicare program as a laboratory and paid under the CLFS. Of these unique NPI-level entities, 93 percent (approximately 247,000) are enrolled as a physician office laboratory, 1 percent (approximately 2,700) are enrolled as independent laboratories while the remaining 6 percent (approximately 16,000) are attributed to other types of laboratories such as those operating within a rural health clinic or a skilled nursing facility. Given our estimate that the low expenditure threshold will exclude approximately 95 percent of physician office laboratories and approximately 55 percent of independent laboratories from having to report applicable information, approximately 12,400 physician office laboratories (247,000 × .05) would be an applicable laboratory and approximately 1,200 independent laboratories (2,700 × .45) would an applicable laboratory for an estimated total of approximately 13,600 applicable laboratories.

According to the National Association of Insurance Commissioners, there were 859 domestic insurers in the United States in 2015.[4] While it is difficult to ascertain how many private payors and private payor rates there are for each applicable laboratory, we understand from an inquiry to an association representing laboratories that each applicable laboratory will bill approximately 1,500 different private insurers. We note that this estimate presumes a finite number of different private payors that may have an agreement with different entities, therefore significantly increasing the total amount of different private insurers. For example, a private insurer may have separate agreements with Federal, State, and County governments, as well as different agreements with various private sector companies. In our estimate, these different agreements are counted as separate private insurers. Some laboratories may bill more or fewer private payors, but we believe this is a reasonable number based on the information furnished to us. For simplicity, we also assume that each applicable laboratory is paid a single private payor rate by each private payor for each laboratory test during a data collection period.

Additionally, although we expect applicable information (that is, private payor rates and associated volume) to be reported by applicable laboratories on nearly all of the approximately 1300 tests on the CLFS, it seems likely that most applicable laboratories will not have private payor rates for each test on the CLFS and that a small number of tests will have the highest volume and more associated private payor rates. For instance, based on 2013 Medicare claims data, 25 tests accounted for over 85 percent of the total allowed services paid on the CLFS. Assuming that all of the estimated applicable laboratories (approximately 13,600) would report a single private payor rate for each of the most common 25 laboratory tests paid on the CLFS, we estimate there would be approximately 37,500 data points reported per applicable laboratory (25 laboratory test rates × 1,500 private payors) and approximately 510 million total data points reported for all applicable laboratories (13,600 estimated applicable laboratories × estimated 37,500 data points per applicable laboratory). As these 510 million data points are for the 25 laboratory tests that account for 85 percent of the volume of tests paid on the CLFS, we would expect the total number of data points to be closer to 600 million (510 million/0.85) when accounting for the remaining laboratory tests paid under the CLFS. We believe the most time consuming of the activities related to data collection would be done by an office staff worker such as an Office Clerk (Occupational Category 49–9061 according to the Bureau of Labor Statistics earning and average hourly wage of $15.33). We believe this wage rate would not include benefits so there would be an additional cost assuming benefits.[5] However, it is very difficult to estimate the number of hours this would require so we are unfortunately unable to come up with a cost estimate of this burden to include in the RIA. In addition, and we acknowledge that there is a high degree of uncertainty around our analysis as a result of the dearth of available data on which to estimate costs.

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[4] National Association of Insurance Commissioners, 2015 Insurance Department Resources Uses Report, Volume 1, page 27.

Additionally, we recognize that requirements set forth by section 1834A of the Act may necessitate changes to IT systems and other administrative changes for laboratories to implement the reporting requirements of section 1834A of the Act. One commenter indicated that IT systems changes resulting from the data collection and reporting requirements could cost $300,000 and as much as $600,000 to implement. We presume that the majority of applicable laboratories would have IT systems and would not need to rely extensively on a manual payment remittance process. Although the information we received from the comments regarding the cost of IT changes was insightful, it was insufficient to develop a cost estimate for data collection and reporting activities for the entire laboratory industry.

E. Alternatives Considered

This final rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding sections of this final rule provide descriptions of the statutory provisions that are addressed, identify policies where the statute recognizes the Secretary's discretion, present the rationale for our policies and, where relevant, alternatives that were considered.

In developing this final rule, we considered numerous alternatives to the final policies. Key areas where we considered alternatives include the organizational level associated with an applicable laboratory, authority to develop a low volume or low expenditure threshold to reduce reporting burden for small businesses, whether to include coinsurance amounts as part of the applicable information, the definition of the initial reporting period for ADLTs, and how to set rates for CDLTs for which the agency receives no applicable information. Below, we discuss alternative policies considered. We recognize that all of the alternatives considered could have a potential impact on the cost or savings under the CLFS. However, we do not have any private payor rate information with which to price these alternative approaches.

1. Definition of Applicable Laboratory—TIN vs. NPI

As discussed previously in this section, we proposed to define an applicable laboratory at the TIN level rather than the NPI level because we believed that reporting applicable information would be less burdensome for applicable laboratories. However, as discussed in detail in section II.A of this final rule, in response to public comments, we revised our proposal and, as a final policy adopted in this final rule, we are defining applicable laboratory at the NPI level while maintaining that the TIN-level entity will be the reporting entity. We believe that having the TIN-level entity report applicable information for all of the NPI-level entities in its organization that are applicable laboratories will not affect or diminish the quality of the applicable information reported and should produce the same applicable information as reporting individually at the NPI level.

2. Authority To Develop a Low Volume or Low Expenditure Threshold To Reduce Reporting Burden for Small Businesses

We proposed to exercise our authority to develop a low expenditure threshold to exclude small businesses from having to report applicable information. Specifically, we proposed that any entity that would otherwise be an applicable laboratory, but that received less than $50,000 in Medicare revenues under sections 1834A and 1833(h) of the Act (the CLFS) for tests furnished during a data collection period, would not be an applicable laboratory. We considered the alternative of not proposing a low volume or low expenditure threshold which would require all entities meeting the definition of applicable laboratory to report applicable information to us. However, by proposing a low expenditure threshold we were able to substantially reduce the number of entities required to report applicable information to us (94 percent of physician office laboratories and 52 percent of independent laboratories would not be required to report applicable information) while retaining a high percentage of Medicare utilization (that is, 96 percent of CLFS spending on physician office laboratories and more than 99 percent of CLFS spending on independent laboratories) from applicable laboratories that would be required to report. We did not pursue a low volume threshold because we believed it could potentially exclude laboratories that perform a low volume of very expensive tests from reporting applicable information.

As discussed section II.A of this final rule, we are revising the low expenditure threshold consistent with defining an applicable laboratory at the NPI level rather than the TIN level. We are also revising the low expenditure threshold consistent with our decision in this final rule to change the data collection period from 12 months to 6 months, which will also reduce the reporting burden for reporting entities (see detailed discussion in section II.D. of this final rule). With these changes, the low expenditure threshold is reduced from $50,000 in the proposed rule to $12,500 in this final rule. As we found for the proposed rule, the application of the low expenditure threshold will significantly reduce the number of laboratories qualifying as applicable laboratories and substantially reduce the reporting burden for small businesses. We estimate that the low expenditure threshold of $12,500 adopted in this final rule will exclude approximately 95 percent of physician office laboratories and approximately 55 percent of independent laboratories from having to report applicable information, while retaining a high percentage of Medicare utilization (that is, approximately 92 percent of CLFS spending on physician office laboratories and approximately 99 percent of CLFS spending on independent laboratories). Additionally, as discussed in section II.A., for a single laboratory that offers and furnishes an ADLT, the $12,500 threshold will not apply with respect to the ADLT. This means, if the laboratory otherwise meets the definition of applicable laboratory, whether or not it meets the low expenditure threshold, it will be considered an applicable laboratory with respect to the ADLT it offers and furnishes, and must report applicable information for its ADLT. If it does not meet the threshold, it will not be considered an applicable laboratory with respect to all the other CDLTs it furnishes.

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[5] United States Department of Labor, Bureau of Labor Statistics, Occupational and Employment Wages, May, 2015, 43–9061 Office Clerks, General. *http://www.bls.gov/oes/current/oes439061.htm.*

3. Definition of New ADLT Initial Period

As explained in section II.D. of this final rule, section 1834A(d)(1)(A) of the Act requires an "initial period" of three quarters during which payment for new ADLTs is based on the actual list charge for the laboratory test. The statute does not specify when this initial period of three quarters is to begin. Section 1834A(d)(2) of the Act requires reporting of applicable information not later than the last day of the Q2 of the new ADLT initial period. These private payor rates will be used to determine the CLFS rate after the new ADLT initial period ends. We considered starting the new ADLT initial period on the day the new ADLT is first performed (which in most cases would be after a calendar quarter begins). However, as noted previously in this final rule, if we were to start the new ADLT initial period after the beginning of a calendar quarter, the 2nd quarter would also begin in the midst of a calendar quarter, requiring the laboratory to report applicable information from the middle of the calendar quarter rather than on a calendar quarter basis. Further, if a new ADLT initial period of three quarters would also end during a calendar quarter, the laboratory would start getting paid the weighted median rate in the middle of the calendar quarter rather at the beginning of a calendar quarter. This may be burdensome and confusing for laboratories. As such, we believe that the new ADLT initial period should start and end on the basis of a calendar quarter (for example, January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31) for consistency with how private payor rates will be reported and determined for CDLTs (on the basis of a calendar year which is four quarters aggregated) and how CLFS rates will be paid (also on the basis of a calendar year). As discussed in section II.D., we are revising the definition of new ADLT initial period in § 414.502 to mean a period of 3 calendar quarters that begins on the first day of the first full calendar quarter following the later of the date a Medicare Part B coverage determination is made or ADLT status is granted by us.

4. Recoupment of Payment for New ADLTs

As discussed in section II.H.4. of this final rule, the statute specifies that if, after a new ADLT initial period, the Secretary determines the payment amount that was applicable during the initial period (the test's actual list charge) was greater than 130 percent of the payment amount that is applicable after such period (based on private payor rates), the Secretary shall recoup the difference between those payment amounts for tests furnished during the initial period. We proposed to recoup the entire amount of the difference between the actual list charge and the weighted median private payer rate. After consideration of public comments, we revised our proposed policy so that, for tests furnished during the new ADLT initial period, we will pay up to 130 percent of the weighted median private payor rate. That is, if the actual list charge is subsequently determined to be greater than 130 percent of the weighted median private payor rate, we will recoup the difference between the actual list charge and 130 percent of the weighted median private payer rate. As we currently do not have information upon which to develop a cost estimate for this final recoupment policy, we cannot estimate how this policy will impact future payments under the CLFS. We do not anticipate many laboratory tests will meet the criteria for being an ADLT, therefore, we do not expect this final recoupment policy will have a significant impact on total CLFS spending.

5. Medicare Payment for Tests Where No Applicable Information Is Reported

As discussed in section II.B of this final rule, in the event we do not receive applicable information for a laboratory test that is provided to a Medicare beneficiary, we will use crosswalking and gapfilling using the definitions in § 414.508(b)(1) and (2) to establish a payment rate on or after January 1, 2018, which will remain in effect until the year following the next data reporting period. This policy includes the situation where we receive no applicable information for tests that were previously priced using gapfilling or crosswalking or where we had previously priced a test using the weighted median methodology. If we receive no applicable information in a subsequent data reporting period, we will use crosswalking or gapfilling methodologies to establish the payment amount for the test. That is, if in a subsequent data reporting period, no applicable information is reported, we will reevaluate the basis for payment, of crosswalking or gapfilling, and the payment amount for the test.

In exploring what we would do if we receive no applicable information for a CDLT, we alternatively considered carrying over the current payment amount for a test under the current CLFS, the payment amount for a test (if one was available) using the weighted median methodology based on applicable information from the previous data reporting period, or the gapfilled or crosswalked payment amount. However, we did not adopt this approach because we believe carrying over previous payment rates would not reflect changes in costs or pricing for the test over time. As noted previously, we believe reconsidering payment rates for tests in these situations is consistent with the purpose of section 1834A of the Act, which requires us to periodically reconsider CLFS payment rates. In this final rule, we finalized our proposal for using crosswalking and gapfilling in the event we do not receive applicable information for a laboratory test.

6. Phased-In Payment Reduction

As discussed previously, we proposed to use the NLAs for purposes of applying the 10 percent reduction limit to CY 2017 payment amounts instead of using local fee schedule amounts. As previously explained, we believed the statute intends CLFS rates to be uniform nationwide, which is why it precludes any geographic adjustment. We proposed that if the weighted median calculated for a CDLT based on applicable information for CY 2017 would be more than 10 percent less than the CY 2016 NLA for that test, we would establish a Medicare payment amount for CY 2017 that is no less than 90 percent of the NLA (that is, no more than a 10 percent reduction). We proposed, for each of CY 2017 through 2022, we would apply the applicable percentage reduction limitation to the Medicare payment amount for the preceding year. The alternative would have been to apply the 10 percent reduction limitation to the lower of the NLA or the local fee schedule amount. This option would retain some of the features of the current payment methodology. Under this option, though, the Medicare payment amounts may be local fee schedule amounts, so there could continue to be regional variation in the Medicare payment amounts for CDLTs. We believe that Medicare infrequently pays less than the NLA and there would be significant burden for CMS to establish systems logic to establish transition payment based on the lesser of the local fee schedule amount or the NLA. For this reason, and because we believe the statute intends there to be uniform national payment for CLFS services, we decided not to adopt this option.

As discussed in section II.D of this final rule, we are moving the implementation date of the private payor-based rates for the CLFS by one year, to January 1, 2018. Therefore we are making a corresponding change to the phase-in of payment reductions timetable to reflect the January 1, 2018 implementation date. We are codifying this change from the proposed rule in § 414.507(d) to indicate that a maximum payment reduction per year of 10 percent applies for years 2018 through 2020 and a maximum payment reduction per year of 15 percent applies for years 2021 through 2023.

We did not receive comments on the proposed rule regarding the phased-in reduction provisions. Therefore, we adopted our proposal for phased-in reduction, along with the above changes to the timetable, as final policy.

F. Accounting Statement and Table

As required by OMB Circular A–4 (available on the Office of Management and Budget Web site at: *http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf*), we have prepared an accounting statement in Table 14 to illustrate the impact of this final rule. The following table illustrates the estimated amount of change in CLFS spending under the policies set forth in this final rule.

TABLE 14—ACCOUNTING STATEMENT: ESTIMATED CLINICAL LABORATORY FEE SCHEDULE TRANSFERS FROM CY 2016 TO CY 2025 ASSOCIATED WITH THE FINALIZED CHANGES TO THE CLINICAL LABORATORY FEE SCHEDULE AS DESCRIBED IN SECTION 1834A OF THE ACT

Category	Estimates	Year dollar		
Transfers		Year dollar	Discount rate (percent)	Period covered
Federal Annualized Monetized Transfers (in millions)	−385	2016	3	2016–2025
	−374	2016	7	2016–2025
From Whom to Whom	Federal Government to Entities that Receive Payments under the Medicare Clinical Laboratory Fee Schedule			

	Estimate (in millions)											5-year impact	10-year impact
	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2016–2020	2016–2025
FY Cash Impact (with MC)													
Part B:													
Benefits	....	....	....	(520)	(930)	(820)	(760)	(830)	(570)	(380)	(410)	(2,270)	(5,220)
Premium													
Offset	....	....	....	130	230	200	190	210	140	90	100	560	1,290
Total Part B	....	....	....	(390)	(700)	(620)	(570)	(620)	(430)	(290)	(310)	(1,710)	(3,930)

G. Cost to the Federal Government

We are creating a data collection system, developing HCPCS codes for laboratory tests when needed, convening a FACA advisory committee to make recommendations on how to pay for new CDLTs including reviewing and making recommendations on applications for ADLTs, and undertaking other implementation activities. To implement these new standards, we anticipate initial federal start-up costs to be approximately $4 million per year. Once implemented, ongoing costs to collect data, review ADLTs, maintain data collection systems, and provide other upkeep and maintenance services will require an estimated $3 million annually in federal costs. We will continue to examine and seek comment on the potential impacts to both Medicare and Medicaid.

H. Conclusion

The changes we adopt in this final rule will affect suppliers who receive payment under the CLFS, primarily independent laboratories and physician offices. We are limited in our ability to determine the specific impact on different classes of suppliers at this time due to the data limitations noted earlier in this section. However, we anticipate that the updated information through this data collection process in combination with the exclusion of adjustments (geographic adjustment, budget neutrality adjustment, annual update, or other adjustment that may apply under other Medicare payment systems), as described in section 1834A(b)(4)(B) of the Act, will reduce aggregate payments made through the CLFS, and therefore, some supplier level payments. We note that this final rule includes changes that may affect different laboratory test suppliers differently, based on the types of tests they provide.

The previous analysis, together with the remainder of the preamble, provides a Regulatory Flexibility Analysis. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amend 42 CFR chapter IV as set forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

■ 2. The heading for subpart G is revised to read as follows:

Subpart G—Payment for Clinical Diagnostic Laboratory Tests

§ 414.1 [Amended]

■ 3. Section 414.1 is amended by adding "1834A—Improving policies for clinical diagnostic laboratory tests" in numerical order.

■ 4. Section 414.500 is revised to read as follows:

§ 414.500 Basis and scope.

This subpart implements provisions of 1833(h)(8) of the Act and 1834A of the Act—procedures for determining the basis for, and amount of, payment for a clinical diagnostic laboratory test (CDLT).

■ 5. Section 414.502 is amended by adding the definitions of "Actual list charge," "Advanced diagnostic laboratory test (ADLT)," "Applicable information," "Applicable laboratory," "Data collection period," "Data reporting period," "National Provider Identifier," "New advanced diagnostic laboratory test (ADLT)," "New ADLT initial period," "New clinical diagnostic laboratory test (CDLT)," "Private payor," "Private payor rate," "Publicly available rate," "Reporting entity," "Single laboratory," "Specific HCPCS code," "Successor owner," and "Taxpayer Identification Number (TIN)" in alphabetical order to read as follows:

§ 414.502 Definitions.

* * * * *

Actual list charge means the publicly available rate on the first day the new advanced diagnostic laboratory test (ADLT) is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date.

Advanced diagnostic laboratory test (ADLT) means a clinical diagnostic laboratory test (CDLT) covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the single laboratory that designed the test or a successor owner of that laboratory, and meets one of the following criteria:

(1) The test—

(i) Is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins;

(ii) When combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies);

(iii) Provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and

(iv) May include other assays.

(2) The test is cleared or approved by the Food and Drug Administration.

Applicable information, with respect to each CDLT for a data collection period:

(1) Means—

(i) Each private payor rate for which final payment has been made during the data collection period;

(ii) The associated volume of tests performed corresponding to each private payor rate; and

(iii) The specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test.

(2) Does not include information about a test for which payment is made on a capitated basis.

Applicable laboratory means an entity that:

(1) Is a laboratory, as defined in § 493.2 of this chapter;

(2) Bills Medicare Part B under its own National Provider Identifier (NPI);

(3) In a data collection period, receives more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Parts A and B, Medicare Advantage payments under Medicare Part C, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period from one or a combination of the following sources:

(i) This subpart G.

(ii) Subpart B of this part.

(4) Receives at least $12,500 of its Medicare revenues from this subpart G. Except, for a single laboratory that offers and furnishes an ADLT, this $12,500 threshold—

(i) Does not apply with respect to the ADLTs it offers and furnishes; and

(ii) Applies with respect to all the other CDLTs it furnishes.

Data collection period is the 6 months from January 1 through June 30 during which applicable information is collected and that precedes the data reporting period.

Data reporting period is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period.

National Provider Identifier (NPI) means the standard unique health identifier used by health care providers for billing payors, assigned by the National Plan and Provider Enumeration System (NPPES) in 45 CFR part 162.

New advanced diagnostic laboratory test (ADLT) means an ADLT for which payment has not been made under the clinical laboratory fee schedule prior to January 1, 2018.

New ADLT initial period means a period of 3 calendar quarters that begins on the first day of the first full calendar quarter following the later of the date a Medicare Part B coverage determination is made or ADLT status is granted by CMS.

New clinical diagnostic laboratory test (CDLT) means a CDLT that is assigned a new or substantially revised Healthcare Common Procedure Coding System (HCPCS) code, and that does not meet the definition of an ADLT.

* * * * *

Private payor means:

(1) A health insurance issuer, as defined in section 2791(b)(2) of the Public Health Service Act.

(2) A group health plan, as defined in section 2791(a)(1) of the Public Health Service Act.

(3) A Medicare Advantage plan under Medicare Part C, as defined in section 1859(b)(1) of the Act.

(4) A Medicaid managed care organization, as defined in section 1903(m)(1)(A) of the Act.

Private payor rate, with respect to applicable information:

(1) Is the final amount that is paid by a private payor for a CDLT after all private payor price concessions are applied and does not include price concessions applied by a laboratory.

(2) Includes any patient cost sharing amounts, if applicable.

(3) Does not include information about denied payments.

Publicly available rate means the lowest amount charged for an ADLT that is readily accessible in such forums as a company Web site, test registry, or price listing, to anyone seeking to know how much a patient who does not have the benefit of a negotiated rate would pay for the test.

Reporting entity is the entity that reports tax-related information to the Internal Revenue Service (IRS) using its Taxpayer Identification Number (TIN) for its components that are applicable laboratories.

Single laboratory, for purposes of an ADLT, means:

(1) The laboratory, as defined in 42 CFR 493.2, which furnishes the test, and that may also design, offer, or sell the test; and

(2) The following entities, which may design, offer, or sell the test:

(i) The entity that owns the laboratory.

(ii) The entity that is owned by the laboratory.

Specific HCPCS code means a HCPCS code that does not include an unlisted CPT code, as established by the American Medical Association, or a Not Otherwise Classified (NOC) code, as established by the CMS HCPCS Workgroup.

* * * * *

Successor owner, for purposes of an ADLT, means a single laboratory, that has assumed ownership of the single laboratory that designed the test or of the single laboratory that is a successor owner to the single laboratory that designed the test, through any of the following circumstances:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law.

(2) *Unincorporated sole proprietorship.* Transfer of title and property to another party.

(3) *Corporation.* The merger of the single laboratory corporation into another corporation, or the consolidation of two or more corporations, including the single laboratory, resulting in the creation of a new corporation. Transfer of corporate stock or the merger of another corporation into the single laboratory corporation does not constitute change of ownership.

Taxpayer Identification Number (TIN) means a Federal taxpayer identification number or employer identification number as defined by the IRS in 26 CFR 301.6109–1.

■ 6. Section 414.504 is added to read as follows:

§ 414.504 Data reporting requirements.

(a) In a data reporting period, a reporting entity must report applicable information for each CDLT furnished by its component applicable laboratories during the corresponding data collection period, as follows—

(1) For CDLTs that are not ADLTs, every 3 years beginning January 1, 2017.

(2) For ADLTs that are not new ADLTs, every year beginning January 1, 2017.

(3) For new ADLTs—

(i) Initially, no later than the last day of the second quarter of the new ADLT initial period; and

(ii) Thereafter, every year.

(b) Applicable information must be reported in the form and manner specified by CMS.

(c) A laboratory seeking new ADLT status for its test must, in its new ADLT application, attest to the actual list charge.

(d) To certify data integrity, the President, CEO, or CFO of a reporting entity, or an individual who has been delegated authority to sign for, and who reports directly to, such an officer, must sign the certification statement and be responsible for assuring that the data provided are accurate, complete, and truthful, and meets all the reporting parameters described in this section.

(e) If the Secretary determines that a reporting entity has failed to report applicable information for its applicable laboratories, or made a misrepresentation or omission in reporting applicable information for its applicable laboratories, the Secretary may apply a civil monetary penalty to a reporting entity in an amount of up to $10,000 per day, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. 114–74, November 2, 2015), for each failure to report or each such misrepresentation or omission. The provisions for civil monetary penalties that apply in general to the Medicare program under 42 U.S.C. 1320a–7b apply in the same manner to the laboratory data reporting process under this section.

(f) CMS or its contractors will not disclose applicable information reported to CMS under this section in a manner that would identify a specific payor or laboratory, or prices charged or payments made to a laboratory, except to permit the Comptroller General, the Director of the Congressional Budget Office, and the Medicare Payment Advisory Commission, to review the information, or as CMS determines is necessary to implement this subpart, such as disclosures to the HHS Office of Inspector General or the Department of Justice for oversight and enforcement activities.

(g) Applicable information may not be reported for an entity that does not meet the definition of an applicable laboratory. For a single laboratory that offers and furnishes an ADLT that is not an applicable laboratory except with respect to its ADLTs, the applicable information of its CDLTs that are not ADLTs may not be reported.

■ 7. Section 414.506 is amended by revising the introductory text and paragraph (d)(1), and adding paragraphs (d)(3) and (4) and (e) to read as follows:

§ 414.506 Procedures for public consultation for payment for a new clinical diagnostic laboratory test.

For a new CDLT, CMS determines the basis for and amount of payment after performance of the following:

* * * * *

(d) * * *

(1) Proposed determinations with respect to the appropriate basis for establishing a payment amount for each code, with an explanation of the reasons for each determination, the data on which the determinations are based, including recommendations from the Advisory Panel on CDLTs described in paragraph (e) of this section, and a request for written public comments within a specified time period on the proposed determination; and

* * * * *

(3) On or after January 1, 2018, in applying paragraphs (d)(1) and (2) of this section, CMS will provide an explanation of how it took into account the recommendations of the Advisory Panel on CDLTs described in paragraph (e) of this section.

(4) On or after January 1, 2018, in applying paragraphs (d)(1) and (2) of this section and § 414.509(b)(2)(i) and (iii) when CMS uses the gapfilling method described in § 414.508(b)(2), CMS will make available to the public an explanation of the payment rate for the test.

(e) CMS will consult with an expert outside advisory panel, called the Advisory Panel on CDLTs, composed of an appropriate selection of individuals with expertise, which may include molecular pathologists researchers, and individuals with expertise in laboratory science or health economics, in issues related to CDLTs. This advisory panel will provide input on the establishment of payment rates under § 414.508 and provide recommendations to CMS under this subpart.

■ 8. Section 414.507 is added to read as follows:

§ 414.507 Payment for clinical diagnostic laboratory tests.

(a) *General rule.* Except as provided in paragraph (d) of this section, and §§ 414.508 and 414.522, the payment rate for a CDLT furnished on or after January 1, 2018, is equal to the weighted median for the test, as calculated under paragraph (b) of this section. Each payment rate will be in effect for a period of one calendar year for ADLTs and three calendar years for all other CDLTs, until the year following the next data collection period.

(b) *Methodology.* For each test under paragraph (a) of this section for which applicable information is reported, the weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory.

(c) The payment amounts established under this section are not subject to any adjustment, such as geographic, budget neutrality, annual update, or other adjustment.

(d) *Phase-in of payment reductions.* For years 2018 through 2023, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

(1) 2018—10 percent of the national limitation amount for the test in 2017.

(2) 2019—10 percent of the payment rate established in 2018.

(3) 2020—10 percent of the payment rate established in 2019.

(4) 2021—15 percent of the payment rate established in 2020.

(5) 2022—15 percent of the payment rate established in 2021.

(6) 2023—15 percent of the payment rate established in 2022.

(e) There is no administrative or judicial review under sections 1869 and 1878 of the Social Security Act, or otherwise, of the payment rates established under this subpart.

(f) Effective April 1, 2014, the nominal fee that would otherwise apply for a sample collected from an individual in a Skilled Nursing Facility (SNF) or by a laboratory on behalf of a Home Health Agency (HHA) is $5.

(g) For a CDLT for which CMS receives no applicable information, payment is made based on the crosswalking or gapfilling methods described in § 414.508(b)(1) and (2).

(h) For ADLTs that are furnished between April 1, 2014 and December 31, 2017, payment is based on the crosswalking or gapfilling methods described in § 414.508(a).

■ 9. Section 414.508 is revised to read as follows:

§ 414.508 Payment for a new clinical diagnostic laboratory test.

(a) For a new CDLT that is assigned a new or substantially revised code between January 1, 2005 and December 31, 2017, CMS determines the payment amount based on either of the following:

(1) *Crosswalking.* Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code.

(i) CMS assigns to the new CDLT code, the local fee schedule amounts and national limitation amount of the existing test.

(ii) Payment for the new CDLT code is made at the lesser of the local fee schedule amount or the national limitation amount.

(2) *Gapfilling.* Gapfilling is used when no comparable existing CDLT is available.

(i) In the first year, Medicare Administrative Contractor-specific amounts are established for the new CDLT code using the following sources of information to determine gapfill amounts, if available:

(A) Charges for the CDLT and routine discounts to charges;

(B) Resources required to perform the CDLT;

(C) Payment amounts determined by other payors; and

(D) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.

(ii) In the second year, the test code is paid at the national limitation amount, which is the median of the contractor-specific amounts.

(iii) For a new CDLT for which a new or substantially revised HCPCS code was assigned on or before December 31, 2007, after the first year of gapfilling, CMS determines whether the contractor-specific amounts will pay for the test appropriately. If CMS determines that the contractor-specific amounts will not pay for the test appropriately, CMS may crosswalk the test.

(b) For a new CDLT that is assigned a new or substantially revised HCPCS code on or after January 1, 2018, CMS determines the payment amount based on either of the following until applicable information is available to establish a payment amount under the methodology described in § 414.507(b):

(1) *Crosswalking.* Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code.

(i) CMS assigns to the new CDLT code, the payment amount established under § 414.507 of the comparable existing CDLT.

(ii) Payment for the new CDLT code is made at the payment amount established under § 414.507.

(2) *Gapfilling.* Gapfilling is used when no comparable existing CDLT is available.

(i) In the first year, Medicare Administrative Contractor-specific amounts are established for the new CDLT code using the following sources of information to determine gapfill amounts, if available:

(A) Charges for the test and routine discounts to charges;

(B) Resources required to perform the test;

(C) Payment amounts determined by other payors;

(D) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant; and

(E) Other criteria CMS determines appropriate.

(ii) In the second year, the CDLT code is paid at the median of the Medicare Administrative Contractor-specific amounts.

■ 10. Section 414.509 is amended by revising the introductory text and paragraphs (b)(2)(i) through (v) to read as follows:

§ 414.509 Reconsideration of basis for and amount of payment for a new clinical diagnostic laboratory test.

For a new CDLT, the following reconsideration procedures apply:

* * * * *

(b) * * *

(2) * * *

(i) By April 30 of the year after CMS makes a determination under § 414.506(d)(2) or paragraph (a)(3) of this section that the basis for payment for a CDLT will be gapfilling, CMS posts interim Medicare Administrative Contractor-specific amounts on the CMS Web site.

(ii) For 60 days after CMS posts interim Medicare Administrative Contractor-specific amounts on the CMS Web site, CMS will receive public comments in written format regarding the interim Medicare Administrative Contractor-specific amounts.

(iii) After considering the public comments, CMS will post final Medicare Administrative Contractor-specific amounts on the CMS Web site.

(iv) For 30 days after CMS posts final Medicare Administrative Contractor-specific payment amounts on the CMS Web site, CMS will receive reconsideration requests in written format regarding whether CMS should reconsider the final Medicare Administrative Contractor-specific payment amount and median of the Medicare Administrative Contractor-specific payment amount for the CDLT.

(v) Considering reconsideration requests received, CMS may reconsider its determination of the amount of payment. As the result of a reconsideration, CMS may revise the median of the Medicare Administrative Contractor-specific payment amount for the CDLT.

* * * * *

■ 11. Section 414.522 is added to subpart G to read as follows:

§ 414.522 Payment for new advanced diagnostic laboratory tests.

(a) The payment rate for a new ADLT—

(1) During the new ADLT initial period, is equal to its actual list charge.

(2) Prior to the new ADLT initial period, is determined by the Medicare Administrative Contractor based on information provided by the laboratory

seeking new ADLT status for its laboratory test.

(b) After the new ADLT initial period, the payment rate for a new ADLT is equal to the weighted median established under the payment methodology described in § 414.507(b).

(c) If, after the new ADLT initial period, the actual list charge of a new ADLT is greater than 130 percent of the weighted median established under the payment methodology described in § 414.507, CMS will recoup the difference between the ADLT actual list charge and 130 percent of the weighted median.

(d) If CMS does not receive any applicable information for a new ADLT by the last day of the second quarter of the new ADLT initial period, the payment rate for the test is determined either by the gapfilling or crosswalking method as described in § 414.508(b)(1) and (2).

Dated: May 26, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: June 14, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–14531 Filed 6–17–16; 4:15 pm]

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Part IV

General Services Administration

48 CFR Parts 501, 515, 516, et al.
General Services Administration Acquisition Regulation (GSAR); Transactional Data Reporting; Final Rule

GENERAL SERVICES ADMINISTRATION

48 CFR Parts 501, 515, 516, 538, and 552

[GSAR Change 74; GSAR Case 2013–G504; Docket No. 2014–0020; Sequence No. 1]

RIN 3090–AJ51

General Services Administration Acquisition Regulation (GSAR); Transactional Data Reporting

AGENCY: Office of Acquisition Policy, General Services Administration.

ACTION: Final rule.

SUMMARY: The General Services Administration (GSA) is amending the General Services Administration Acquisition Regulation (GSAR) to include clauses that require vendors to report transactional data from orders placed against certain Federal Supply Schedule (FSS) contracts, Governmentwide Acquisition Contracts (GWACs), and Governmentwide Indefinite-Delivery, Indefinite-Quantity (IDIQ) contracts.

Transactional data refers to the information generated when the Government purchases goods or services from a vendor. It includes specific details such as descriptions, part numbers, quantities, and prices paid for the items purchased. GSA has experimented with collecting transactional data through some of its contracts and found it instrumental for improving competition, lowering pricing, and increasing transparency. Accordingly, GSA will now test these principles on a broader base of its contracting programs. This move supports the Government's shift towards category management by allowing it to centrally analyze what it buys and how much it pays, and thereby identify the most efficient solutions, channels, and sources to meet its mission critical needs.

GSA will introduce a new Transactional Data Reporting clause to its FSS contracts in phases, beginning with a pilot for select Schedules and Special Item Numbers. Participating vendors will no longer be subject to the existing requirements for Commercial Sales Practices (CSP) disclosures and Price Reductions clause (PRC) basis of award monitoring, resulting in a substantial burden reduction. Stakeholders have identified the CSP and PRC requirements as some of the most burdensome under the Schedules program. These actions represent the most significant change to the Schedules program in the past two decades. GSA has also created a Transactional Data Reporting clause for all new GWACs and Governmentwide IDIQ contracts and may apply the clause to any existing contracts in this class that do not contain other transactional data requirements.

DATES: This rule is effective June 23, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. Matthew McFarland, Senior Policy Advisor, GSA Acquisition Policy Division, at 202–690–9232 or *matthew.mcfarland@gsa.gov.*

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I. Overview

The purpose of the Transactional Data Reporting rule is to transform price disclosure and related policies for GSA's Federal Supply Schedule (FSS) contracts, Governmentwide Acquisition Contracts (GWACs), and Governmentwide Indefinite-Delivery, Indefinite Quantity (IDIQ) contracts, in order to improve the value taxpayers receive when purchases are made using these vehicles. The rule contains new clauses that require vendors to electronically report certain specific details on transactions under these GSA contracts, such as the descriptions of goods or services acquired, part numbers, quantities, and prices paid. GSA will use this added market intelligence to make smarter buying decisions and share the information with its agency customers so they can also make smarter buying decisions when utilizing GSA's contract vehicles.

The rule also seeks to eliminate burden associated with current pricing disclosure and tracking requirements for thousands of entities, particularly small businesses that sell to agencies through the FSS program, the Government's largest purchasing channel for commercial products and services. In Fiscal Year 2015 alone, GSA's FSS contracts accounted for $33 billion in sales, or more than 7 percent of all federal contract spending. Accordingly, the rule provides for a measured and managed phase-out of disclosures and tracking currently required by the Commercial Sales Practices (CSP) format and the Price Reductions clause (PRC), and the associated practice of negotiating pricing based on a model where the Government strives to secure the vendor's most favored pricing and maintain this position for the life of the contract. Instead, GSA is adopting a more dynamic market driven pricing model, where vendors submit prices paid by Government customers through a new Transactional Data Reporting clause[1] and the Government uses this data, along with other pricing information, to ensure a vendor's offered price is competitive relative to other vendors selling the same or similar items or services.

The Transactional Data Reporting clause is being implemented under the Schedules program on a pilot basis, to begin not less than 60 days after the publication date of the rule. Participation in the pilot will initially be voluntary for existing Schedule contract holders, and those who participate and comply with the Transactional Data Reporting requirements will not provide CSPs or be subject to the PRC basis of award tracking customer provision. The pilot will involve eight Schedules, including the information technology Schedule 70 and the Professional Services Schedule (Schedule 00CORP), and will reach approximately 30 percent of GSA's FSS contracts that account for more than 40 percent of GSA the FSS sales volume.

FSS contracts managed by the Department of Veterans Affairs are not included in the pilot and therefore will not be impacted by changes made by this rule to waive application of the CSP and PRC tracking customer provision.

For GSA's non-FSS Governmentwide vehicles, a Transactional Data Reporting clause[2] is immediately available. The new clause will be applied to solicitations for covered vehicles issued on or after the effective date of the rule. Existing contract vehicles containing other transactional data requirements have the option of incorporating the new clause through bilateral modifications.

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[1] GSAR clause 552.238–74, Industrial Funding Fee and Sales Reporting (Alternate I) (48 CFR 552.238–74 Alternate I).

The Transactional Data Reporting final rule follows a proposed rule published by GSA in the **Federal Register** at 80 FR 11619, on March 4, 2015.[3] The proposed rule sought to eliminate the PRC tracking customer provision but retained the Government's right to request CSP disclosures. In response to the proposed rule, many public commenters concurred with the need for a change to Schedules pricing policies, as well as the need for a model that leverages modern analytics and 21st century technology, but a number of commenters asserted that GSA's projections of burden reduction were significantly overstated. They explained that the continued requirement to maintain the CSP, coupled with the Government's right to regularly demand updated information, would significantly limit the relief contractors would realize from waiver of the PRC's tracking requirements. Other commenters raised concern that elimination of these historical pricing tools would thwart GSA's ability to gauge how its prices relate to commercial sales, and as a result, put the Government at a greater risk of paying less competitive prices for commercial goods and services.

After careful review of the public comments, which are discussed in greater detail in Section V of this document,[4] and additional deliberation with Government stakeholders, GSA has modified the proposed rule to authorize in the final rule the phased elimination of both the CSP and the PRC tracking customer provision, as opposed to just the PRC's tracking requirements, as the proposed rule would have provided. Phase-out of these requirements will be subject to the results of a pilot, as was discussed in the preamble to the proposed rule. However, the pilot has been broadened to be more reflective of the varied goods and services offered and sold through the Schedules program, and will allow GSA to more effectively evaluate the likely impact of the intended transformation before making any final determinations.

Transactional Data Reporting is an attempt to embrace modern technology while moving away from outmoded practices. When first introduced in the 1980s, the CSP and PRC helped GSA and its customer agencies maintain advantageous pricing from original equipment manufacturers that held the vast majority of FSS contracts. However, changes in what the Government buys and shifts in the federal marketplace have eroded the effectiveness of these tools over time. Additionally, vendors repeatedly single out these pricing tools as among the most complicated and burdensome requirements in federal contracting. By contrast, Transactional Data Reporting provides a less burdensome alternative. The rule adds a total of $15 million a year in costs for two classes of contracts, FSS ($12 million a year) and non-FSS ($3 million a year). FSS vendors are currently subject to the CSP and PRC reporting requirements that are being eliminated, resulting in a $44 million a year burden reduction. Factoring in the $12 million a year increase for new reporting requirements, this equates to a $32 million a year net burden reduction for those FSS vendors ($12 million − $44 million = −$32 million). However, non-FSS vendors are not subject to the CSP and PRC requirements and therefore are not receiving any burden reduction, but are seeing a $3 million a year reporting burden for the new requirements. As a result, the net burden reduction reduces to $29 million a year when accounting for all vendors subject to the rule ($12 million + $3 million − $44 million = −$29 million).

In all, the Transactional Data Reporting rule will result in an estimated burden reduction of $29 million a year, which consists of a projected $15 million a year compliance burden[5] minus the estimated $44 million a year burden for the CSP and PRC requirements being waived for vendors participating in the FSS pilot.[6]

Equally important, GSA's experience using horizontal pricing techniques, where it compares a vendor's offered price to those offered by other vendors, has proved to be a more effective model. This includes a growing body of experience with transactional data that points to improved acquisition outcomes, from smarter demand management, to better pricing and reduced price variation, and opportunities to develop more effective buying strategies. Section II.B of this document provides several examples of how the Government has successfully employed transactional data-fueled horizontal pricing techniques.

To ensure a measured and manageable transition to use of transactional data in lieu of the CSP and PRC, the final rule will be implemented through a multi-layered phase-in process built around the pilot as follows:

- First, the pilot will be evaluated against a series of metrics that will include, but not be limited to, changes in price, sales volume, and small business participation, as well as macro use of transactional data by category managers and teams to create smarter buying strategies such as consumption policies. GSA's Senior Procurement Executive will regularly evaluate progress against these metrics in consultation with the Administrator for Federal Procurement Policy and other interested stakeholders to determine whether to expand, limit, or discontinue the program. No expansion of the pilot or action to make Transactional Data Reporting a permanent fixture on the Schedules will occur prior to the careful evaluation of at least one year of experience with the pilot.
- Second, Schedules will enter the pilot on a rolling basis. At least thirty days prior to applying the pilot to a Schedule or Special Item Number, vendors will be given notice on Interact, GSA's platform for exchanging information with Schedule vendors.[7]
- Third, the new Transactional Data Reporting requirements will be mandatory only for new Schedule contracts awarded after the Schedule becomes subject to the pilot and at the time to extend the term of the Schedule contract. Initially, vendors holding existing contracts under pilot Schedules will be encouraged to enter via a bilateral contract modification so they can begin to take advantage of the

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[2] GSAR clause 552.216–75, Transactional Data Reporting (48 CFR 552.216–75).

[3] See GSAR Case 2013–G504; Docket 2014–0020; Sequence 1 (80 FR 11619 (Mar. 4, 2015)).

[4] See section V. Public Comments Overview and Discussion.

[5] See Section VIII.B, Annualized Public Burden Estimates.

[6] The CSP and PRC burden estimates are from Information Collection 3090–0235, FSS Pricing Disclosures. The annual public reporting burden for the CSP and PRC, excluding FSS vendors participating in the Transactional Data Reporting pilot, is $57.66 million. If FSS pilot vendors were still subject to the CSP and PRC reporting requirements, the total annual public reporting burden would be $101.69 million. The FSS pilot vendors' share of the total CSP and PRC reporting burden is based upon their share of the GSA FSS fiscal year 2015 sales volume, 43.2 percent. The annual $44.03 million reporting burden reduction attributed to this rule is 43.2 percent of the $101.69 million annual reporting burden if it were applied to the entire GSA FSS program. More information about Information Collection 3090–0235 can be found at *http://www.reginfo.gov/public* by searching "ICR" for "3090–0235".

[7] GSA Interact can be accessed at *https://interact.gsa.gov.*

reduced burden of not having to comply with the CSP and PRC.

- Fourth, use of the transactional data will be introduced to federal buyers in stages, starting with category managers to provide them with insight into the assorted options available for satisfying common requirements and support smarter buying strategies, such as demand management, that promote the most efficient methods for meeting the Government's needs. The data will then be shared with FSS contracting officers, followed by agency ordering offices. Each of these buying groups will receive tailored training on the proper use of transactional data. In all cases, training will emphasize that prices paid information is just one information point that must be considered in conjunction with other factors such as total cost, quantity discounts, desired performance levels, unique terms and conditions or product attributes, delivery schedule, customer satisfaction, and other relevant information. Contracting officers will be encouraged to discuss with the offeror perceived variances between offered prices, transactional data, and existing contract-level prices, in order to evaluate whether other attributes (*e.g.*, superior warranties, quantity discounts, *etc.*) justify awarding higher prices.

Finally, GSA is amending its pricing instructions in the General Services Administration Acquisition Manual (GSAM) to place greater emphasis on price analysis when negotiating prices with Schedule vendors and, in particular, the need to specifically consider (i) offered prices on FSS contracts or Governmentwide contracts for the same or similar items or services, (ii) prices paid, as it becomes available under this rule, and (iii) commercial data sources providing publicly available pricing information. The GSAM guidance will also reiterate that the contracting officer is responsible for ensuring pricing is fair and reasonable. Accordingly, if a contracting officer is unable to make this determination based on data available to them through GSA's tools or available commercial pricing information, they will retain the right, as the Federal Acquisition Regulation (FAR) has always provided, to request additional pricing information, such as data other than certified cost and pricing data.

A fuller discussion of these issues is presented in the following sections of this document, including GSA's analysis of alternatives, an overview of the rule's implementation, a discussion of public comments, and an examination of the reporting burden.

GSA's primary statutory authorities for the FSS program are 41 U.S.C. 152(3), Competitive Procedures, and 40 U.S.C. 501, Services for Executive Agencies. For GWACs, GSA is an executive agent designated by the Office of Management and Budget pursuant to 40 U.S.C. 11302(e). Furthermore, 40 U.S.C. 121(c) authorizes GSA to prescribe regulations for its other multi-agency contracts, including Governmentwide IDIQ contracts. Finally, this rule is included in GSA's report under Executive Order 13563, Improving Regulation and Regulatory Review, which directs each federal agency to consider "how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome." GSA's retrospective plan and updates to the plan can be found at *www.gsa.gov/improvingregulations.*

II. Background

A. Category Management

Currently, the Federal Government acquires goods and services worth hundreds of billions in dollars through millions of individual transactions conducted by thousands of contracting units across hundreds of federal agencies and commissions. Most buying offices operate independently, conducting procurements without regard to the experiences of their counterparts. Functions such as industry outreach, market research, requirements development, negotiations, and contract award are repetitively performed, without coordination, across the acquisition landscape. Ongoing contract duplication leaves vendors navigating a diverse array of procedures and requirements, driving up administrative costs that ultimately manifest in higher prices.

In response, the Office of Federal Procurement Policy (OFPP) introduced a new vision for federal purchasing to fundamentally shift managing individual purchases and prices across thousands of procurement units to buying as one through category management.[8] The initiative entails grouping commonly-purchased goods and services into centrally coordinated categories. The Category Management Leadership Council (CMLC), established by OFPP, has defined the underlying principles of category management, which are supported by this rule:

1. Optimizing existing contract vehicles (including replacement or elimination of duplicate or underperforming contracts) and driving more optimal use of contract vehicles.
2. Improving data collection efforts and analysis to drive improvements in categories of spend to increase savings and reduce duplication.
3. Leveraging industry/commercial intelligence and key partner relationships.
4. Maximizing customer insights and relationships to bring more spend under management and improve offerings and value.
5. Growing and sharing expertise.[9]

The CMLC has identified the following ten first-tier, or Level 1, categories that account for $270 billion, or approximately two-thirds, of total contract spending:

- Information Technology (IT).
- Professional Services.
- Security and Protection.
- Facilities & Construction.
- Industrial Products and Services.
- Office Management.
- Transportation and Logistics Services.
- Travel and Lodging.
- Human Capital.
- Medical.[10]

To ensure Governmentwide harmonization, Level 1 categories will be led by a manager responsible for developing category-specific strategies. Within each Level 1 category are several Level 2 categories. For example, the Level 1 IT category includes Level 2 categories such as IT Software and IT Consulting. In concert with their respective category manager, Level 2 category teams will provide expert analysis, identify best-in-class sourcing solutions, and facilitate the dissemination of best practices, leading to smarter buying across the Government.[11]

For example, OFPP issued *Category Management Policy 15–1: Improving the Acquisition and Management of Common Information Technology: Laptops and Desktops.* In Fiscal Year 2014, agencies awarded more than 10,000 contracts and orders totaling $1.1

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[8] See Office of Management and Budget memorandum, "Transforming the Marketplace: Simplifying Federal Procurement to Improve Performance, Drive Innovation and Increase Savings", December 4, 2014, available at *http://www.whitehouse.gov/sites/default/files/omb/procurement/memo/simplifying-federal-procurement-to-improve-performance-drive-innovation-increase-savings.pdf*).

[9] See "Government-wide Category Management, Guidance Document, Version 1.0," Office of Management Budget, May 2015, available at *https://hallways.cap.gsa.gov/information/Gov-wide_CM_Guidance_V1.pdf.*

[10] See "Taking Category Management Government-Wide", January 7, 2015, available at *https://www.whitehouse.gov/blog/2015/01/07/taking-category-management-government-wide-0.*

[11] See "Government-wide Category Management, Guidance Document, Version 1.0," Office of Management Budget, May 2015, available at *https://hallways.cap.gsa.gov/information/Gov-wide_CM_Guidance_V1.pdf.*

billion for laptops and desktops. In addition to contract duplication, price variation is also an issue since the prices paid for laptops of the same configuration could range from $450 to $1,300, or almost 300 percent. A category team led by the National Aeronautics and Space Administration (NASA), with subject matter experts from across the Government, was established and came up with the following requirements:

1. Standardize laptop and desktop configurations for common requirements. Through an extensive data analysis, the category team determined five standard configurations could satisfy 80 percent of the Government's laptop needs.
2. Reduce the number of contracts for laptops and desktops by consolidating purchasing and using a few number of high-performing—or best in class—contracts. With limited exceptions, all agencies are prohibited from issuing new solicitations for laptops and desktops, and civilian agencies must use NASA Solutions for Enterprise-Wide Procurement (SEWP), GSA Schedule 70, or National Institutes of Health (NIH) Chief Information Officer-Commodities and Solutions (CIO–CS).
3. Develop and modify demand management processes to optimize price and performance. Agencies are encouraged to adopt smarter buying strategies, such as adopting uniform refresh cycles and aggregating demand to support leveraged buying events.[12]

In another example, the Professional Services category team within GSA consolidated its offerings in two areas, the Professional Services Schedule (PSS) and the One Acquisition Solution for Integrated Services (OASIS) vehicle. The PSS is the result of combining eight separate Schedules under one umbrella, and in the process eliminating more than 700 duplicative contracts. This promotes efficiency in a number of ways. GSA can now focus its resources on improving the user experience under its contracts. Vendors, especially small businesses, now need to manage fewer contracts to fully access the professional services market, lowering their administrative burden. Finally, customers can meet their mission needs through a less fragmented purchasing channel. Likewise, OASIS provides flexibility for federal buyers seeking to streamline their acquisition strategies by eliminating duplicative contracts. In Fiscal Year 2015, GSA supported the Army and Air Force in moving more than $350 million in combined contract sales under the OASIS vehicle. OASIS has also allowed the Air Force to forgo extending five of its IDIQ contracts and the Department of Homeland Security has chosen OASIS as the successor to its Technical, Acquisition, and Business Support Services (TABSS) IDIQ contract.

The reduction in duplicative and inefficient contracts also removes barriers to entry into the federal marketplace, especially for small businesses. The Government Accountability Office (GAO) reports the costs of being on multiple contract vehicles ranged from $10,000 to $1,000,000 due to increased bid and proposal, and administrative costs.[13] Consequently, as category management streamlines procurement channels and vendors realize lower administrative costs, small businesses in particular will benefit from a leveling of the playing field. Small business participation is a key component of all category management strategies and care will be taken to ensure small businesses maintain access to the federal marketplace as duplicative contracts are eliminated.

Nevertheless, as category management continues to permeate the acquisition landscape, a critical ingredient for its success must be obtained: Transactional data.

B. Necessity and Value of Transactional Data

A critical component of category management, and smarter buying in general, is the availability of transactional data, which shows the details of purchases at the line-item level. It includes details such as descriptions, quantities, and prices paid for the items purchased. More than providing leverage for Government buyers to negotiate lower prices, transactional data underlies the business intelligence used to inform smarter buying strategies.

Transactional data provides the Government insight into its purchasing patterns, allowing it to identify the most efficient solutions, channels, and sources to meet mission critical needs. As previously noted, two key category management principles are optimizing existing contract vehicles and reducing contract duplication.[14] With transactional data, the Government can analyze its consumption patterns, evaluate and compare purchasing channels, and identify best-in-class solutions. Thereafter, the Government can leverage its buying power to achieve taxpayer savings as it concentrates its purchases through fewer channels, which will in turn provide lower administrative costs for federal contractors.

Category managers will also use transactional data to develop demand management strategies that offer more optimal solutions for satisfying common requirements. For example, GSA's Domestic Delivery Services 2 (DDS2) program illustrates how transactional data can provide valuable insight into purchasing patterns and offer opportunities to develop more effective procurement strategies. In Fiscal Year 2009, 90 percent of revenue through the Domestic Delivery Services contracts was for more expensive, express air shipments, with less costly ground shipments accounting for the remaining 10 percent. However, after analyzing the actual buying practices through transactional data, the Government was able to change its consumption behavior to spend less by foregoing unnecessary express air shipments. By Fiscal Year 2015, air shipments shrank to 60 percent of revenue and 46 percent of total shipments, while ground shipments grew to 40 percent of revenue and 54 percent of total shipments.

Transactional data can also be leveraged to reduce price variation and lower costs. As exhibited by the 300 percent laptop price variance, Government buyers often rely on asymmetric information, which results from one party possessing better information than the other. In response, GSA began pioneering transactional data reporting on several of its contract vehicles. Combined with sourcing strategies and enhanced competition, GSA successfully instituted dynamic pricing models, where prices are continually adjusted based on transactional data, resulting in less variation and lower prices. Examples of this success include:

- Office Supplies 2 (OS2) and Office Supplies 3(OS3), with direct savings increasing from 10 percent in Fiscal Year 2010 to nearly 30 percent by Fiscal Year 2015.
- Federal Strategic Sourcing Initiative (FSSI) Wireless: This contract delivered

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[12] See Office of Management and Budget Memorandum M–16–02, "Category Management Policy 15–1: Improving the Acquisition and Management of Common Information Technology: Laptops and Desktops", October 16, 2015, available at *https://www.whitehouse.gov/sites/default/files/omb/memoranda/2016/m-16-02.pdf.*

[13] See GAO report GAO–10–367, "Contracting Strategies, Data and Oversight Problems Hamper Opportunities to Leverage Value of Interagency and Enterprisewide Contracts," April 2010, available at *http://www.gao.gov/new.items/d10367.pdf.*

[14] See "Government-wide Category Management, Guidance Document, Version 1.0," Office of Management Budget, May 2015, available at *https://hallways.cap.gsa.gov/information/Gov-wide_CM_Guidance_V1.pdf.*

a 21 percent savings rate in its first year of operation (Fiscal Year 2014), which then increased to 26 percent by its second year. Other agencies that adopted FSSI Wireless achieved savings up to 38 percent from their previous contract prices while reducing the number of devices managed.

- Commercial Satellite Communications (COMSATCOM): Customers save an average of 34 percent compared to GSA Schedule contract prices and better understand spend details. The availability of transactional data under COMSATCOM is already contributing to a reduction in duplicative contracts.

However, transactional data does not transform the federal acquisition system into a lowest-price procurement model. The Federal Acquisition Regulation (FAR) has a stated vision "to deliver on a timely basis the best value product or service to the customer, while maintaining the public's trust and fulfilling public policy objectives."[15] The Government's preference will continue to be "best value," or as defined in the FAR, "the expected outcome of an acquisition that, in the Government's estimation, provides the greatest overall benefit in response to the requirement."[16] Transactional data is viewed in the context of each procurement, taking into account desired terms and conditions, performance levels, past customer satisfaction, and other relevant information. Using and understanding the data will help inform requirements definition and reduce excess consumption.

C. Imperative for Innovation

In Fiscal Year 2015, Government agencies ordered nearly $40 billion in goods and services through GSA's Federal Supply Schedules, Governmentwide Acquisition Contracts (GWACs), and Governmentwide Indefinite-Delivery, Indefinite-Quantity (IDIQ) contracts. GSA's Federal Supply Schedule program, commonly known as GSA Schedules or Multiple Award Schedules (MAS), accounted for approximately $33 billion of those sales, making it the Government's most used commercial-item purchasing channel. Consistent with the broader effort to transform the federal marketplace, GSA is innovating its suite of Governmentwide contract vehicles.

While GSA has a number of policies in place to help its buyers and agency users to secure best value for the taxpayer, and other regulatory actions in process to improve the Schedules program, two limitations in current pricing practices make achievement of this goal unnecessarily challenging: (1) Insufficient attention to "horizontal pricingI"—the ability to compare one vendor's pricing to that of other vendors—and (2) lack of visibility into prices paid by other customers.

Insufficient Attention to Horizontal Pricing: GSA currently relies on a "vertical" pricing model to establish price reasonableness on its FSS contracts, which entails comparing a contractor's prices and price-related terms and conditions with those offered to their other customers. Through analysis and negotiations, GSA establishes a favorable pricing relationship in comparison to one of the contractor's customers or category of customers.

Until recently, when vendors first submitted an FSS offer, minimal consideration was given to the relative competitiveness of the vendor's prices to other vendors (*i.e.*, horizontal pricing). Instead, the FSS program primarily collects aggregate sales information through Commercial Sales Practices (CSP) disclosures, which include a broad disclosure of discounts vendors offer to commercial customers for similar products and services.[17] GSA's negotiation objective is to achieve a company's best price—*i.e.*, the price given to its most favored customer—who buys in quantities and under conditions similar to those of the Government.[18] Contractors are then required, under the Price Reductions clause (PRC), to monitor their pricing over the life of the contract and provide the Government with the same price reductions that they give to the class of the contractor's commercial customers upon which the original contract award was predicated.[19] In addition to the "tracking customer" requirement, the PRC allows vendors to voluntarily reduce prices to the Government and for the Government to request a price reduction at any time during the contract period, such as where market analysis indicates that lower prices are being offered or paid for the same items under similar conditions.

Pricing disclosures, such as the CSP and its predecessors, along with the PRC, have served as the bedrock of the Schedules program pricing approach for at least as far back as the 1980s. With limited other means of data collection available, they served as a way to ensure fair and reasonable pricing through the life of a contract with the goal of achieving most favored customer pricing. For many years, CSP disclosures and the PRC tracking customer feature were critical mechanisms for achieving advantageous pricing from original equipment manufacturers (OEMs) that held the vast majority of FSS contracts. However, these tools predate the Federal Acquisition Streamlining Act of 1994 (FASA)[20] and the subsequent procedures in FAR part 12, which aim to "establish policies more closely resembling those of the commercial marketplace."[21] For instance, FASA required the Government to only ask for information other than cost and pricing data as needed.

Moreover, a number of factors have eroded the effectiveness of these tools over time, including: (i) The significant growth of contracts held by resellers with little or no commercial sales against which to negotiate most favored customer pricing; (ii) the prevalence of sales for commercial-off-the-shelf products or other commercial items for which the Government is not a market driver; and (iii) the fact that these practices tie pricing for reductions to sales of single items and play little role in blanket purchase agreements and other higher-volume leveraged buying by agencies to achieve greater savings and reduce administrative costs.

When it comes to contract administration, the Government, and other customers in the category to which the Government is most typically aligned under the PRC, tends to receive voluntary price reductions from the vendor as a result of general market forces. In other words, prices are reduced under the voluntary provisions of the PRC as a result of competitive market forces, not under the mandatory tracking customer provisions.

Vendors have also singled out these pricing tools as among the most complicated and burdensome requirements in federal contracting, including during a 2014 national online dialogue sponsored by the Chief Acquisition Officers Council to identify ways of improving how the Government does business with its contractors. A number of contractors contended that the one-size-fits all application of these tools to all Schedules runs counter to the spirit of the FASA and its implementing policies in FAR part 12, such as by requesting detailed pricing information only after determining that more readily available data is not sufficient to establish fair and reasonable pricing. Some noted that the proliferation of Schedule resellers has occurred, in part, out of an effort by OEMs to shield them from what they see as an overly complex and burdensome process that has created a punitive relationship between the Government and its suppliers.

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[15] Federal Acquisition Regulation section 1.102 (48 CFR 1.102).

[16] Federal Acquisition Regulation section 2.101 (48 CFR 2.101).

[17] General Services Administration Acquisition Regulation section 515.408(a)(2) (48 CFR 515.408(a)(2)).

[18] General Services Administration Acquisition Regulation section 538.270 (48 CFR 538.270).

[19] General Services Administration Acquisition Regulation clause 552.238–75 (48 CFR 552.238–75).

[20] Public Law 103–355.

[21] Federal Acquisition Regulation section 12.000 (48 CFR 12.000).

GSA recognized the deficiencies of its vertical pricing model and has begun implementing horizontal pricing initiatives for its FSS contracts. For example, over the past year GSA has launched the Competitive Pricing Initiative (CPI) and the Contract Awarded Labor Category Tool (CALC):

- CPI aims to identify and address price variability across the Schedules program. The initiative is built around a Formatted Product Tool (FPT) that identifies pricing outside a range determined to be acceptable for identical items; vendors whose prices exceed the acceptable range are then notified of their comparative pricing. Currently, this initiative applies only to products, while services will be addressed at a later date. Moving forward, FSS contracting officers will utilize available horizontal pricing data from the FPT for certain categories of supplies when conducting price analysis, in addition to other price analysis techniques already employed in compliance with the FAR and GSAR. The FSS contracting officer's final determination will also take into account non-price elements, such as materially different terms, quantities, and market and economic factors. CPI will also allow FSS contracting officers to identify where a vendor's offered pricing is outside the range determined to be acceptable for identified products and services. After a vendor has been notified, they will be given the opportunity to use this market intelligence to make their offered pricing more competitive. Equally important, vendors will have the chance to advise if they have a unique value proposition, such as speedier deliveries, guarantees, or quantity that warrants a higher price.
- CALC is a market research tool that searches a database of awarded FSS contract prices for 48,000 labor categories from more than 5,000 FSS contracts under the Professional Services Schedule. Rather than sifting through contract files or searching GSA Advantage!® for comparable pricing, Government contracting professionals can now use CALC to return a multitude of comparable contract prices within a matter of seconds. Additionally, these search results can be filtered by relevant criteria such as years of experience and education level. Over time, greater enhancements are anticipated, such as adding geographic filters.

GSA has made tremendous progress on the horizontal price analysis front over the past year, but tools such as CPI and CALC only support segments of the FSS program and only analyze contract-level prices. Although GSA establishes fair and reasonable prices on its Governmentwide contracts, the program is designed with the intent of ordering activities negotiating further discounts at the time of the instant requirement. While in many respects this is a significant strength of the program, at times, the absence of good pricing information contributes to negative perceptions of the program, and as result, contract duplication. Consequently, transactional data is needed to perform a horizontal analysis of the actual prices paid for goods and services acquired through GSA contract vehicles.

Lack of transparency in prices previously paid: The FAR has long emphasized the need for contracting officers to conduct price analysis as part of their responsibility to determine offered prices are fair and reasonable. Price analysis requires contracting officers to obtain and analyze data on the prices at which the same or similar items have been sold, but until recently, little effort was made to share prices previously paid by agencies throughout the Government. As a result, contracting officers generally lack critical information when making these important determinations.

Though the specifics vary, several of GSA's non-FSS contracts now require vendors to report transactional data, including Alliant, Alliant Small Business, Connections II, Custom SATCOM Solutions (CS2), Custom SATCOM Solutions—Small Business (CS2–SB), Office Supply Third Generation (OS3), and One Acquisition Solution for Integrated Services (OASIS). However, these requirements are applied through their respective solicitations without the benefit of a dedicated, standard GSAR clause, resulting in inconsistency.

Continuous innovation is imperative for the FSS program. In 2010, the Multiple Award Schedule (MAS) Blue Ribbon Advisory Panel, which included representatives from the Government's largest buying agencies—the Department of the Defense, Department of Homeland Security, Department of the Interior, Department of the Treasury, and Department of Education—and industry, recommended that "the GSA Administrator remove the Price Reduction Clause from the MAS program supply contracts for products in phases as the GSA Administrator implements recommendations for competition and price transparency at the Schedule contract level and the order level." That same year, the Government Accountability Office (GAO) issued a report recommending GSA collect "prices paid" data on FSS orders and make this information available to FSS contract negotiators and customer agencies.[22] Over the next few years, GSA explored alternatives for collecting transactional data through the FSS program before ultimately deciding to pursue incorporating a transactional data reporting requirement in its FSS contracts.

D. Transactional Data Reporting: Proposed Rule and Public Meeting

On March 4, 2015, GSA issued a proposed rule to require transactional data reporting on its FSS contracts and non-FSS contract vehicles—Governmentwide Acquisition Contracts (GWACs) and Governmentwide Indefinite-Delivery, Indefinite-Quantity (IDIQ) contracts. The rule proposed for non-FSS contracts would have been immediately implemented but rolled out on a pilot basis for the FSS program under select Schedules. For FSS contracts, the requirement would be paired with an alternate Price Reductions clause that did not include the tracking customer feature, although GSA would have had the right to request CSP disclosures at any time.[23]

On April 17, 2015, a public meeting was held at GSA headquarters in Washington, DC, to discuss the proposed rule. Nearly 200 companies, organizations, Government agencies, and interest groups were represented. In general, industry representatives opposed the transactional data reporting requirement but supported the proposed PRC changes. Government procurement representatives supported the rule, while oversight entities expressed concern with the potential reporting burden and PRC changes.[24]

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[22] See U.S. Government Accountability Office report GAO–10–367, "Data and Oversight Problems Hamper Opportunities to Leverage Value of Interagency and Enterprisewide Contracts," April 2010, available at *http://www.gao.gov/products/GAO-10-367.*

[23] See GSAR Case 2013–G504 (80 FR 11619 (Mar. 4, 2015)).

[24] See the public meeting transcript at *http://www.regulations.gov/#!documentDetail;D=GSA-GSAR-2014-0020-0024.*

Following an extension to the public comment period,[25] GSA received 26 comment letters on the proposed rule, including comments from industry associations, contractors, individuals, Government stakeholders, and other interested groups.

III. Final Rule Overview

GSA is adopting new requirements for transactional data reporting on its FSS, GWAC, and Governmentwide IDIQ vehicles:

- For FSS contracts, a new transactional data reporting clause, GSAR Alternate I, 552.238–74 Industrial Funding Fee and Sales Reporting (Federal Supply Schedule), will be paired with changes to FSS pricing disclosure requirements. Specifically, FSS vendors subject to the Transactional Data Reporting rule will no longer provide CSP disclosures and will no longer be subject to the PRC tracking customer provision. These changes will be initially implemented for select Schedules and Special Item Numbers on a pilot basis.
- For GWACs and Governmentwide IDIQs, a new clause, GSAR 552.216–75 Transactional Data Reporting, will apply to all new GWACs and Governmentwide IDIQs and may be applied to any existing contracts in this class that do not contain other transactional data clauses.

A. Summary of Changes Made at the Final Rule Stage

The following is a summary of changes made in response to public comments regarding the proposed rule:

CSP Disclosures: FSS vendors will no longer provide CSP disclosures for contracts subject to the new Transactional Data Reporting clause, 552.238–74 Alternate I. This is in addition to pairing the new reporting clause with the new Price Reductions clause (552.238–75) Alternate II, which does not include the basis of award tracking customer requirement. The GSAR sections requiring CSP disclosures and clauses 552.238–75 and 552.238–75 Alternate I (the PRC versions that include the tracking customer provision) have been updated to exclude contracts subject to the new FSS reporting clause, 552.238–74 Alternate I.

GSA has also concluded the horizontal pricing ability afforded by Transactional Data Reporting would not only exceed the PRC tracking customer provision benefits, it could also alleviate the need for CSP disclosures when combined with automated commercial data sources, new data analytic tools, and improved price analysis policy. For the Schedules pilot, pairing Transactional Data Reporting with a removal of CSP disclosures and the PRC tracking customer provision will result in an average annual burden reduction of approximately $32 million for participating FSS vendors.[26] Furthermore, implementing the FSS pilot without the existing CSP and PRC requirements lowers the Government's burden by about $3 million a year.[27]

Data Reporting and Fee Remittance Timelines: Both Transactional Data Reporting clauses (552.216–75 and 552.238–74 Alternate I) now require vendors to report transactional data within 30 calendar days after the last day of the calendar month. Additionally, the non-FSS clause (552.216–75) now states a GSA representative will provide the contractor with specific written procedural instructions on remitting the Contract Access Fee (CAF) within 60 days of award or inclusion of this clause in the contract, including the deadline by which the contractor must remit the CAF, although the deadline specified in the written procedural instructions will be no less than 30 days after the last day of the month. Previously, GSA proposed for contractors subject to both clauses to report transactional data within 15 calendar days after the end of the calendar month. Non-FSS contractors were to remit any CAF due within 15 calendar days after the end of the calendar month. FSS contractors were to remit any Industrial Funding Fee (IFF) due within 30 calendar days after the end of each quarter.

GSA increased the monthly reporting window from 15 to 30 calendar days in response to comments stating the proposed 15-day window did not allow enough time to compile, analyze, and report transactional data. GSA opted to not require monthly IFF remittance because doing so would disproportionately harm small businesses, many of whom remit fees based on accrued billings before they actually receive payments from their Government customers. The non-FSS clause (552.216–75) does not specify CAF remittance frequency—those instructions will be provided within 60 days after award or inclusion of the clause in the contract—but ensures contractors have at least 30 days after the last day of the month to remit the CAF.

Clause Language: GSA made several revisions to the clause language for 552.216–75 and 552.238–74 Alternate I, including a data element "fill-in" for additional elements that requires approval from GSA's Senior Procurement Executive.

Paperwork Reduction Act: GSA increased its Transactional Data Reporting burden estimates. For the proposed rule, GSA's public burden estimates included an average initial setup time of 6 hours and average ongoing monthly reporting times ranging from 2 minutes to 4 hours, depending on a vendor's sales volume.[28] In contrast, the final rule burden estimates include initial average setup times of 8 hours for vendors using manual systems and 240 hours for vendors using automated systems, and average ongoing monthly reporting times ranging from 15 minutes to 48 hours, depending on a contractor's sales volume and reporting system type.

B. Alternatives Analysis

GSA determined it is necessary to obtain and analyze transactional data for purchases made through its contract vehicles in order to support the Government's category management vision and improve acquisition outcomes in general. However, following the April 17, 2015 public meeting and subsequent receipt of the public comments, GSA was compelled to further evaluate the spectrum of alternatives for Transactional Data Reporting, ranging from withdrawing the rule in favor of different approaches for obtaining the data to applying the new reporting clauses without corresponding changes to existing disclosure requirements. Ultimately, the decision to proceed hinged on considerations including, but not limited to, alternatives for collecting transactional data; the burden associated with reporting transactional data; opportunities to reduce burden through changes to existing disclosure requirements, and the associated impacts of those changes; effects on small businesses; and the benefits of collecting transactional data for non-standard products and services.

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[25] See GSAR Case 2013–G504 (80 FR 25994 (May 6, 2015)).

[26] $32 million does not include costs for non-FSS contracts. It is the result of the FSS burden of the initial pilot implementation ($12.41 million), minus the share of the combined CSP and PRC burden allocated to the FSS pilot vendors ($44.03 million). The total CSP and PRC burden from Information Collection 3090–0235, if it were applied to all GSA FSS vendors, including those participating in the Transactional Data Reporting pilot, would be $101.69 million. The share of that burden allocated to the FSS pilot vendors ($44.03 million) is based on the percentage of the overall FY15 FSS sales accounted for by the FSS pilot vendors (43.2 percent).

[27] $3 million is the result of the Government's annual burden for this rule ($2.34 million) minus the share of the combined CSP and PRC burden for the Government allocated to the FSS pilot contracts ($5.58 million).

[28] See GSAR Case 2013–G504; Docket 2014–0020; Sequence 1 [80 FR 11619 (Mar. 4, 2015)].

The Initial Regulatory Flexibility Analysis published with the proposed rule included an evaluation of alternatives for obtaining transactional data—internal applications; GSA ordering platforms such as eBuy and GSA Advantage!®; the SmartPay credit card purchase program; and upgrades to the Federal Procurement Data System. GSA previously concluded these options would not provide the breadth of data needed to support the Government's objectives or would be unable to do so in the foreseeable future. Since the publication of the proposed rule, GSA reevaluated those alternatives and reached similar conclusions. Additionally, the Government's electronic invoicing initiative [29] was assessed as a potential alternative. However, following meetings regarding electronic invoicing implementation with representatives from the Department of Defense, Department of Energy, Department of Transportation, Department of Treasury, and Department of Veterans Affairs, it was determined these electronic invoicing platforms will not provide a Governmentwide transactional data reporting solution in the near term. Consequently, GSA continued to evaluate solutions that relied on contractor-provided transactional data.

The most common concern, in terms of the number of respondents to the proposed rule, regarded the associated burden of reporting transactional data. In general, commenters felt the burden was underestimated and/or the requirement was too burdensome. To address the concerns with its Transactional Data Reporting burden estimates, GSA reevaluated its methodology and significantly increased its burden estimates.[30] These higher burden projections were a significant concern and reinforced the need to couple Transactional Data Reporting with other significant forms of burden reduction.

A notable concern expressed by industry stakeholders was the retention, and potential increase, of CSP disclosures. GSA noted in the proposed rule it ". . . would maintain the right throughout the life of the FSS contract to ask a vendor for updates to the disclosures made on its commercial sales format (which is used to negotiate pricing on FSS vehicles) if and as necessary to ensure that prices remain fair and reasonable in light of changing market conditions." [31] In response, industry stakeholders indicated retaining CSP disclosures would undercut any burden reduction achieved by eliminating the PRC tracking customer requirement. Specifically, respondents were concerned CSP disclosures will still force them to monitor their commercial prices, which ultimately causes the associated burden for both disclosure requirements.

In the summer of 2015, GSA also began preparing its request to renew the PRC information collection, which is identified under OMB Control Number 3090–0235. The Paperwork Reduction Act requires federal agencies to seek public comment on proposed collections of information from the public and then submit an information collection request (ICR) to the OMB Office of Information and Regulatory Affairs (OIRA). After receiving clearance to proceed, federal agencies must seek public comment and OIRA approval for renewal of these information collections, typically every three years. Since the PRC information collection was last approved in 2012, GSA needed to begin preparing its request to renew the information collection shortly after publishing the Transactional Data Reporting proposed rule. While GSA would have proceeded with a renewal request regardless, the timing did allow for the consideration of the Transactional Data Reporting comments. In particular, GSA agreed with the general industry comment that burdens of the PRC and CSP are related and therefore decided to include CSP disclosure burden estimates with the PRC ICR. GSA also opted to change the name of Information Collection 3090–0235 from "Price Reductions Clause" to "Federal Supply Schedule Pricing Disclosures" to more accurately reflect the scope of the information collected.

Following two **Federal Register** notices requesting comments on the FSS Pricing Disclosures ICR,[32] GSA increased its annual burden estimates for GSA FSS vendors, including those who would participate in the Transactional Data Reporting pilot, from $59 million [33] to $102 million.[34] Yet, Transactional Data Reporting alleviates the need for these FSS pricing disclosures when combined with automated commercial data sources, new data analytic tools, and improved price analysis policy. As a result, GSA decided to pair Transactional Data Reporting with the removal of CSP disclosures and the PRC tracking customer provision, resulting in an average annual burden reduction of $32 million for participating FSS vendors.[35] Furthermore, implementing the FSS pilot without the existing CSP and PRC requirements lowers the Government's burden by about $3 million a year.[36]

Streamlining the existing pricing disclosure requirements is particularly beneficial for small businesses. The current CSP and PRC disclosure requirements are constant, meaning vendors, especially those with a higher number of FSS contract offerings, must bear the burden even if they have little to no sales through their FSS contracts. Thus, small businesses are disproportionately impacted because they account for the bulk of lower volume contracts. Moreover, small businesses, which generally have fewer resources to devote to contract management, will no longer be subjected to the complex CSP and PRC pricing disclosure requirements.

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[29] See Office of Management and Budget memorandum M–15–19, "Improving Government Efficiency and Saving Taxpayer Dollars Through Electronic Invoicing", July 17, 2015, available at *https://www.whitehouse.gov/sites/default/files/omb/memoranda/2015/m-15-19.pdf.*

[30] See Section VIII.B for a discussion of the burden estimates in accordance with Paperwork Reduction Act requirements.

[31] See GSAR Case 2013–G504 (80 FR 25994 (May 6, 2015)).

[32] See 80 FR 72060 (Nov. 18, 2015) and 81 FR 21346 (Apr. 11, 2016).

[33] The 2012 information collection did not provide a cost burden estimate, but if the same hourly rate ($68) was applied to the 2012 time burden, the 2012 cost burden would have been $59,086,560.

[34] The annual public reporting burden for the CSP and PRC, excluding FSS vendors participating in the Transactional Data Reporting pilot, is $57.66 million. If FSS pilot vendors were still subject to the CSP and PRC reporting requirements, the total annual public reporting burden would be $101.69 million. The FSS pilot vendors' share of the total CSP and PRC reporting burden is based upon their share of the GSA FSS fiscal year 2015 sales volume, 43.2 percent. The annual $44.03 million reporting burden reduction attributed to this rule is 43.2 percent of the $101.69 million annual reporting burden if it were applied to the entire GSA FSS program. More information about Information Collection 3090–0235 can be found at *http://www.reginfo.gov/public* by searching "ICR" for "3090–0235".

[35] $32 million does not include costs for non-FSS contracts. It is the result of the FSS burden of the initial pilot implementation ($12.41 million), minus the share of the combined CSP and PRC burden allocated to the FSS pilot vendors ($44.03 million). The total CSP and PRC burden from Information Collection 3090–0235, if it were applied to all GSA FSS vendors, including those participating in the Transactional Data Reporting pilot, would be $101.69 million. The share of that burden allocated to the FSS pilot vendors ($44.03 million) is based on the percentage of the overall FY15 FSS sales accounted for by the FSS pilot vendors (43.2 percent).

[36] $3 million is the result of the Government's annual burden for this rule ($2.34 million) minus the share of the combined CSP and PRC burden for the Government allocated to the FSS pilot contracts ($5.58 million).

Unlike the existing CSP and PRC disclosure requirements, Transactional Data Reporting imposes a progressive burden—one that increases with a vendor's sales volume. Namely, monthly reporting time will increase with a vendor's applicable sales volume, as vendors with lower to no reportable sales will spend little time on monthly reporting, while those businesses with more reportable sales with will face a higher reporting burden. Likewise, setup costs will be a major driver of the new reporting burden, but vendors with little to no activity on their FSS contracts will likely forgo investments in new reporting systems because the reporting burden will not be significantly more than that of the current quarterly sales reporting requirements. Thus, tying the burden to sales volume is particularly beneficial for small businesses, as they hold 80 percent of the total contracts but account for only about 39 percent of the sales.[37]

Finally, consideration was given to whether Transactional Data Reporting should be applied to all of GSA's Governmentwide contract vehicles. Most of GSA's non-FSS Governmentwide vehicles currently have transactional data reporting requirements that exceed those created through this rule, but the new applicable Transactional Data Reporting clause (GSAR clause 552.216–75) will provide a consistent reporting mechanism for future non-FSS vehicles, or for current vehicles that adopt the new clause. For FSS contracts, an analysis was conducted to determine whether Transactional Data Reporting should be considered for all FSS contracts, or only those that include products or services that would allow straightforward comparisons, such as commodities with standard part numbers. The second-most common comment area questioned the utility of collecting transactional data for Schedules where "apples-to-apples" comparisons cannot be made, such as contracts for professional services and complex solutions. While transactional data is most useful for price analysis when comparing like items, it does not mean the data is not useful when perfect comparisons cannot be made. Government buyers and FSS contracting officers will use the data for price analysis and market research, and category managers will use the data for consumption analysis to form demand management strategies, regardless of whether the data can be used for perfect comparisons. An example is the ability to compare labor rates across contract vehicles, which is beginning to bear fruit in the form of reduced contract duplication. Consequently, GSA decided not to limit the prescription of Transactional Data Reporting to certain Schedules or Special Item Numbers.

IV. Final Rule Implementation

A. GWAC and Governmentwide IDIQ Contracts

GSAR clause 552.216–75 Transactional Data Reporting is immediately available for GSA's GWACs and non-FSS Governmentwide IDIQ contracts. It will be applied to all new vehicles in this class—those vehicles with solicitations issued on or after the effective date of this rule—but the current contract vehicles with alternative transactional data provisions may opt to continue using existing reporting requirements. The clause requires contractors to report eleven standard data elements and includes a "fill-in" for additional data elements. However, GSA's Senior Procurement Executive must approve any data elements beyond the standard elements in order for them to be included with a tailored version of the clause. The determination regarding additional data elements will consider the benefits, alternatives, burden, and need for additional rulemaking.

B. FSS Contracts

The new FSS Transactional Data Reporting clause (GSAR clause 552.238–74, Alternate I), along with the corresponding changes to existing pricing disclosure requirements, will be introduced in phases, beginning with a pilot for select Schedules and Special Item Numbers (SINs). The clause requires vendors to report eleven standard data elements and includes a "fill-in" for additional data elements. However, GSA's Senior Procurement Executive must approve any data elements beyond the standard elements in order for them to be included with a tailored version of the clause. The determination regarding additional data elements will consider the benefits, alternatives, burden, and need for additional rulemaking.

The pilot will begin no sooner than July 1, 2016—details will be released at a later date—and will include the following Schedules and SINs:

- Schedule 03FAC, Facilities Maintenance and Management: All SINs.
- Schedule 51 V, Hardware Superstore: All SINs.
- Schedule 58 I, Professional Audio/Video, Telemetry/Tracking, Recording/Reproducing and Signal Data Solutions: All SINs.
- Schedule 72, Furnishing and Floor Coverings: All SINs.
- Schedule 73, Food Service, Hospitality, Cleaning Equipment and Supplies, Chemicals and Services: All SINs.
- Schedule 75, Office Products: All SINs.
- Schedule 00CORP, The Professional Services Schedule: Professional Engineering Services (PES) SINs.
- Schedule 70, General Purpose Information Technology Equipment, Software, and Services: SINs 132 8 (Purchase of New Equipment); 132 32, 132 33, and 132 34 (Software); and 132 54 and 132 55 (Commercial Satellite Communications (COMSATCOM)).

The new reporting clause and corresponding pricing disclosure changes will be applied to newly-awarded contracts for the applicable Schedules/SINs. Existing contracts for the pilot Schedules/SINs will adopt the new reporting clause and corresponding pricing disclosure changes after the execution of a bilateral modification between the vendor and Government.

For the two pilot Schedules that include only select SINs—The Professional Services Schedule and Schedule 70—contracts subject to the Transactional Data Reporting that include those SINs will report transactional data for all SINs under those contracts. For example, a vendor holding a Schedule 70 contract consisting of SINs 132 33 (Perpetual Software License), 132 34 (Maintenance of Software as a Service), and 132 51 (Information Technology Professional Services) will be subject to the Transactional Data Reporting pilot because of the inclusion of Software SINs 132 33 and 132 34. However, this vendor will report transactional data for all SINs—132 33, 132 34, and 132 51. Likewise, vendors holding Professional Services Schedule contracts that include a Professional Engineering Services SIN in conjunction with other SINs under that Schedule (*e.g.*, Environmental Services, Mission Oriented Business Integrated Services, *etc.*) will report transactional data for all SINs under the contract.

The initial pilot will reach approximately 30 percent of GSA's FSS contracts, including Schedules/SINs covering a wide array of goods and services that account for approximately 43 percent of the GSA Schedules sales volume. This scope will enable GSA to evaluate the effectiveness of Transactional Data Reporting before deciding whether to expand, limit, or discontinue the program. Evaluation metrics will include, but not be limited to, changes in price, sales volume, and small business participation, as well as macro use of transactional data by category managers and teams to create smarter buying strategies such as consumption policies. GSA's Senior Procurement Executive will regularly evaluate progress against these metrics in consultation with the Administrator for Federal Procurement Policy and other interested stakeholders to determine whether to expand, limit, or discontinue the program. No expansion of the pilot or action to make Transactional Data Reporting a permanent fixture on the Schedules will occur prior to the careful evaluation of at least one year of experience with the pilot.

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[37] Based on fiscal year 2015 Federal Supply Schedule contract data.

C. Systems

Vendors subject to the new Transactional Data Reporting clauses will be required to electronically report the data, as outlined in the applicable clauses, thirty (30) days after the end of the preceding month; reporting instructions will be posted on the Vendor Support Center Web site (*https://vsc.gsa.gov*). To facilitate Transactional Data Reporting, GSA is launching a new portal that has several differences from the existing 72A Sales Reporting System,[38] including the following:

- A single sign-on for all contracts. The current system requires a different sign-on for each contract.
- Electronic Data Interchange (EDI) upload capability.
- A spreadsheet template that can be downloaded, filled, and uploaded in lieu of manual data entry.
- Vendors with $0 sales during a reporting period can now click a single field to complete the report, as opposed to the current 72A requirement of submitting $0 for each SIN.

The new FSS Transactional Data Reporting clause (552.238–74 Alternate I) requires monthly reporting but quarterly fee remittance, which will also be processed through the new portal. As sales are reported, the portal will calculate a running balance and remind users to submit payment within 30 days after the end of the quarters ending March 31, June 30, September 30, and December 31. However, vendors will have the option to pay-as-you-go, meaning they can voluntarily remit the fees as sales are reported, rather than doing so on a quarterly basis. Portal instructions and training will be posted to GSA's Vendor Support Center.[39]

Transactional data collected through the portal will be accessible only by authorized users and protected in accordance with GSA's information technology security policies. Additionally, GSA intends to share transactional data to the maximum extent allowable to promote transparency and competition while respecting that some data could be exempt from disclosure. Accordingly, a public data extract, containing information that would otherwise be releasable under the Freedom of Information Act (FOIA), will be created for use by the general public;[40] details about the public data extract will be released through a forthcoming notice in the **Federal Register**. The data released to the public will provide valuable market intelligence that can be used by vendors for crafting more efficient, targeted business development strategies that incur lower administrative costs. This will be particularly beneficial for small businesses, which often do not have the resources to invest in dedicated business development staff or acquire business intelligence through third-parties.

D. Procedures

GSA, like other agencies, will use transactional data to support its contracting officers in making smarter decisions when purchasing goods and services. However, GSA's FSS contracting officers will also take this data into consideration when awarding FSS contracts and evaluating requests to adjust pricing and add new items to current contracts. As a result, GSA is developing training for Government buyers and implementing new procedures for its FSS contracting officers. Training and guidance deployed in connection with this rule emphasizes the importance of considering the best overall value (not just unit price) for each procurement, taking into account desired terms and conditions, performance levels, past customer satisfaction, and other relevant information.

Training: GSA is updating relevant courseware on the Federal Acquisition Institute (FAI) and Defense Acquisition University (DAU) portals to educate both customers and GSA contracting officers on how to use the data. Similarly, the courseware on how to use the FSS program and other non-FSS GWACs and multi-agency IDIQs will be updated to educate customers on the new requirements and how they can use the data collected to buy smarter. The external courseware will also highlight the additional value transactional data offers to GSA's FSS and non-FSS contracting programs and emphasize it must be viewed in the context of each procurement, taking into account desired terms and conditions, performance levels, past customer satisfaction, and other relevant information.

Additionally, FAS also has an internal training course aimed at GSA contracting officers awarding and administering FSS contracts—this course will be updated to educate contracting officers on how to conduct analysis on transactional data, as well as how to use these analyses to achieve better pricing on the contracts.

Guidance: FSS contracting officers follow policy from GSA's supplement to the FAR, the General Services Administration Acquisition Manual (GSAM), when evaluating offers for FSS contracts. This includes the GSAR, GSA's regulatory FAR supplement, and non-regulatory acquisition policy, commonly referred to as GSAM guidance.[41] Regulations, such as the GSAR, require formal rulemaking, while non-regulatory policy, like GSAM guidance, does not.[42] For example, GSA contracting officer responsibilities are found at the non-regulatory GSAM 501.602,[43] while the regulatory CSP instructions are found at GSAR 515.408.[44]

In addition to the regulatory changes made through this final rule, non-regulatory instructions for GSA category managers and FSS contracting officers are being incorporated into the GSAM. The category manager guidance will include instructions to use transactional data for category analysis, as well as approval requirements for adding data elements to the new Transactional Data Reporting clauses, including approvals by the head of contracting activity and GSA's Senior Procurement Executive and coordination with the applicable category manager. The FSS contracting officer guidance will give instructions for evaluating offers for FSS contracts when transactional data is available.

One of the objectives of the new FSS contracting officer guidance is to align

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[38] See the 72A Sales Reporting System, accessible at *https://72a.gsa.gov*.

[39] See the Vendor Support Center, accessible at *https://vsc.gsa.gov*.

[40] 5 U.S.C. 552.

[41] See General Services Administration Acquisition Manual section 501.170, available at *https://www.acquisition.gov/?q=browsegsam*.

[42] 41 U.S.C. 1707.

[43] See General Services Administration Acquisition Manual section 501.602, available at *https://www.acquisition.gov/?q=browsegsam*.

[44] 48 CFR 515.408.

FSS offer evaluation procedures with the FAR. Accordingly, FSS contracting officers will be instructed to evaluate the data in the context of each offer, taking into account desired terms and conditions, quantity discounts, unique attributes, socio-economic considerations, and other relevant information. Contracting officers are encouraged to discuss with the offeror perceived variances between offered prices, transactional data, and existing contract-level prices, in order to evaluate whether other attributes (*e.g.*, superior warranties, quantity discounts, *etc.*) justify awarding higher prices.

The new guidance will include an order of preference for information to be used when evaluating FSS offers and establishing negotiating objectives, including the following:

1. Using data that is readily available, in accordance with FAR 15.404–1(b)(2)(ii),[45] including prices paid information on contracts for the same or similar items; contract-level prices on other FSS contracts or Governmentwide contracts for the same or similar items, and commercial data sources providing publicly available pricing information.
2. Performing market research to compare prices for the same or similar items in accordance with FAR 15.404–1(b)(2)(vi).[46]
3. Requesting additional pricing information such as "data other than certified cost or pricing data" (as defined at FAR 2.101[47]) from the offeror in accordance with FAR 15.404–1(b)(2)(vii)[48] when the offered prices cannot be determined to be fair and reasonable based on the data found from other sources.

Traditionally, GSAR section 538.270, Evaluation of multiple award schedule (MAS) offers, has instructed FSS contracting officers to require pricing information through the CSP format and seek the offeror's best price. As these instructions are included in the regulatory portion of the GSAM, this case includes new language for these instructions to specify their use only when the CSP format is included in the solicitation (*i.e.*, for the Schedules and SINs not included in the pilot program). The new offer evaluation instructions belong in the non-regulatory section of the GSAM because they provide supplementary guidance to the FAR and do not impose a regulatory burden on the public. However, even though the GSAM guidance is not subject to public comment and is not included with the regulatory changes of this rule, it will be viewable in tandem with the corresponding GSAR policy on *Acquisition.gov*.[49]

V. Public Comments Overview and Discussion

GSA received 26 comment letters in response to the proposed rule.[50] The breakdown along commenter categories is as follows:

Vendors	9
Industry Associations	8
Individuals	5
Government Stakeholders	2
Other Groups	2

All comments filed were considered, many of which led to the changes described in Section III of this document.[51] The following is an overview of these comments and GSA's responses, organized into groupings that are sorted by the number of commenters, with the first grouping containing the most commenters. GSA's responses to these comments are contained within each grouping.

Burden.

Nineteen commenters provided comments related to the compliance burden.[52] Several questioned GSA's burden projections, stating the compliance estimates were understated and the projected burden reduction was overstated. Multiple commenters stated the Government is shifting the burden of gathering transactional data onto vendors, with some suggesting the burden will lead to higher prices or that vendors should be reimbursed for costs incurred.

The proposed rule contained burden estimates in accordance with the Paperwork Reduction Act, including a one-time average initial setup burden of 6 hours and an average monthly reporting burden of approximately .52 of an hour, or 31 minutes. The ongoing reporting burden for FSS vendors, following a first-year burden for implementation, was estimated to $7.6 million a year. However, the proposed rule coupled the new reporting requirement with the removal of the PRC tracking customer provision, which would have resulted in an estimated burden reduction of $51 million a year if applied to the entire GSA Schedules program.[53]

Most of the commenters weighing in on the burden stated the estimates were significantly underestimated. For example, one association compared the proposed rule's burden estimates with the results of a survey it conducted among some of its members to assess the costs of implemented the requirements set forth in the proposed rule. It reported the following for setup time:

> When asked about the estimated number of hours that their company would require for initial startup to comply with the proposed rule, small business respondents reported that it would take on average 232 hours. Large and medium size contractors estimated that it would take on average 1192 hours. In the context of an average work week, small businesses estimated that it would take nearly 6 weeks for initial setup, which would require limited resources to be diverted to this effort. Large and medium size businesses reported that it would take nearly 8 months on average to setup these systems. The proposed rule suggests that contractors should undertake this compliance burden at "no cost to the government."[54]

That association also reported much higher figures for its monthly reporting estimates:

> In the survey contractors also report a significantly higher number of hours required to do the monthly transactional data reporting than estimated in the proposed rule. Respondents were asked in the survey to estimate the number of hours it would take their company to report the transactional data on a monthly basis. GSA estimated that it would only take 31 minutes per month. However, small businesses reported that it would take 38 hours per month on average. Large and medium size businesses estimated that it would take an average of 68 hours per month—nearly 2 weeks to conduct the reporting.[55]

One commenter also questioned GSA's and ordering agencies' ability to use the data, and GSA's capability to enforce the reporting requirements."[56] Multiple commenters stated they would not realize a net burden reduction when the PRC tracking customer provision is removed. For example, one commenter noted the PRC only requires disclosures when a price reduction is triggered, while this rule will require monthly reporting.[57]

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[45] Federal Acquisition Regulation 15.404–1(b)(2)(ii) (48 CFR 15.404–1(b)(2)(ii)).

[46] Federal Acquisition Regulation 15.404–1(b)(2)(iv) (48 CFR 15.404–1(b)(2)(iv)).

[47] Federal Acquisition Regulation 2.101 (48 CFR 2.101).

[48] Federal Acquisition Regulation section 15.401–1(b)(2)(vii) (48 CFR 15.404–1(b)(2)(vii)).

[49] See the General Services Administration Acquisition Manual, available at *https://www.acquisition.gov/?q=browsegsam.*

[50] See GSAR Case 2013–G504; 80 FR 11619 (Mar. 4, 2015).

[51] See Section III.A, Summary of Changes Made at the Final Rule Stage.

[52] See *e.g.*, ABA Letter, Abt Associates Letter, Allen Letter, ARA Letter, CGP Letter, CODSIA Letter, EA Letter, Experian Letter, GSA OIG Letter, immixGroup Letter, IOPFDA Letter, *Insite.rr.com* Letter, Johnson & Johnson Letter, NDIA Letter, POGO Letter, RTI Letter, SBA Letter, Shepra Letter, SIA Letter.

[53] The $51 million burden reduction was the ongoing FSS reporting burden ($7.6 million) minus the PRC burden of $58.5 million from the 2012 PRC information collection (OMB Control Number 3090–0235). The $7.6 million FSS reporting burden did not include the burden for one-time implementation. The $51 million burden reduction applied to the entire GSA Schedules program and was not adjusted to only account for vendors participating in the FSS pilot.

[54] See CGP Letter.

[55] *Ibid.*

[56] See GSA OIG Letter.

Finally, multiple commenters stated Government is shifting the burden of gathering transactional data onto vendors. Some commenters said this will force industry to charge higher prices to recoup their costs, while others argued vendors should be directly reimbursed for reporting costs.

Response: As a result of these comments, GSA reevaluated its estimation methodology and recalculated the burden based on whether vendors use automated or manual systems to identify and report transactional data. An automated system is one that relies on information technology, such as an accounting system or data management software, to identify and compile reportable data. These systems can tremendously streamline the reporting process but require upfront configuration to perform the tasks, such as coding the data elements to be retrieved. Conversely, a manual system is one that incorporates little to no automation and instead relies on personnel to manually identify and compile the reportable data. An example of a manual system would be an accountant reviewing invoices to identify the reportable data and then transferring the findings to a spreadsheet. In contrast to automation, a manual system requires relatively little setup time but the reporting effort will generally increase with the vendor's sales volume.

The likelihood of a vendor adopting an automated system increases with their applicable sales volume. Vendors with little to no reportable data are unlikely to expend the effort needed to establish an automated reporting system since it will be relatively easy to identify and report a limited amount of data. In Fiscal Year 2015, 32 percent of FSS vendors reported $0 sales, while another 34 percent reported average sales between $1 and $20,000 per month. If the rule were applied to the entire Schedules program, approximately two-thirds, or nearly 11,000 vendors, would have a lower reporting burden. However, as a vendor's applicable average monthly sales increase, they will be increasingly likely to establish an automated system to reduce the monthly reporting burden. Consequently, vendors with higher reportable sales will likely bear a higher setup burden to create an automated system, or absorb a high monthly reporting burden if they choose to rely on manual reporting methods.

This renewed analysis led GSA to increase its burden estimates.[58] For FSS contracts in particular—

- The projected setup time for an automated system increased from an average of 6 hours[59] to an average of 240 hours, and
- The projected monthly reporting time range grew from 0.3 minutes–4 hours to 0.25 hours–48 hours.

However, GSA's estimates are still considerably lower than the estimates provided through the public comments,[60] primarily because—

- At least two-thirds of the potential Transactional Data Reporting participants will have a relatively lower burden (*e.g.*, vendors with lower or no sales), and
- Vendors with higher reporting volume will face lower setup times with a higher monthly reporting burden, or higher setup times with a lower monthly reporting burden. In other words, vendors will not face a higher setup burden and a higher monthly reporting burden to comply with the rule.

This increase in the burden estimates reinforced the need to evaluate existing pricing disclosure requirements that could be rendered obsolete once transactional data is collected. After evaluating these comments and submitting the Federal Supply Schedule Pricing Disclosures information collection request (OMB control number 3090–0235),[61] GSA concluded Transactional Data Reporting would not only exceed the PRC tracking customer provision benefits, it would also alleviate the need for CSP disclosures when combined with automated commercial data sources, new data analytic tools, and improved price analysis policy. Even with the increased Transactional Data Reporting burden estimates, GSA projects an average annual burden reduction of approximately $32 million for FSS pilot vendors when the new Transactional Data Reporting requirements are paired with the removal of CSP disclosures and the PRC tracking customer provision.[62]

As noted in Section III of this document, this proposal is particularly advantageous for small businesses.[63] In order to enter the federal marketplace through the Schedules program, small businesses have traditionally been required to absorb the burden of gathering CSP disclosures and developing robust PRC compliance systems before making even a dollar in revenue through their Schedule contracts. However, under the Transactional Data Reporting model, small businesses entering the Schedules program would not, in most cases, be likely to make significant upfront investments because they will only be impacted after they have won a Schedule order. Additionally, unlike information compiled to populate CSPs, which is created specifically for GSA, the transactional data reported each month is readily available data used to generate invoices.

Regarding the ability of GSA and ordering agencies to use the data, new systems are being deployed to leverage the information. Transactional data reported in accordance with the new clauses will be shared with authorized users to craft smarter buying strategies. GSA is also developing data visualization tools to make the data more user friendly. Within GSA, FAS has established a data analytics team that will assist in the establishment and ongoing analysis of contract-level prices. In terms of oversight, FAS will use many of the same resources it currently deploys to ensure compliance with the existing GSAR clause 552.238–74, Industrial Funding Fee and Sales Reporting.[64]

GSA is pursuing this initiative because obtaining transactional data from its industry partners is the most feasible path the Government can take to implement smarter buying strategies and promote taxpayer value. GSA recognizes the burden that comes with this rule and will continually evaluate ways to minimize the data collection. However, this rule will not lead to higher costs and subsequently higher prices because the changes to the CSP and PRC requirements provide a net burden reduction. To the contrary,

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[57] See immixGroup Letter.

[58] See Section VIII.B for a discussion of the burden estimates in accordance with Paperwork Reduction Act requirements.

[59] The proposed rule setup time estimates did not differentiate between manual and automated reporting systems.

[60] See CGP Letter.

[61] More information about Information Collection 3090–0235 can be found at *http://www.reginfo.gov/public* by searching "ICR" for "3090–0235".

[62] $32 million does not include costs for non-FSS contracts. It is the result of the FSS burden of the initial pilot implementation ($12.41 million), minus the share of the combined CSP and PRC burden allocated to the FSS pilot vendors ($44.03 million). The total CSP and PRC burden from Information Collection 3090–0235, if it were applied to all GSA FSS vendors, including those participating in the Transactional Data Reporting pilot, would be $101.69 million. The share of that burden allocated to the FSS pilot vendors. ($44.03 million) is based on the percentage of the overall FY15 FSS sales accounted for by the FSS pilot vendors (43.2 percent).

[63] See Section III.B, Alternatives Analysis.

[64] General Services Administration Acquisition Regulation clause 552.238–74 (48 CFR 552.238–74).

Transactional Data Reporting, as shown by the results shared in Section II of this document, will lead to lower prices.[65]

Using Transactional Data for Imperfect Comparisons

Fifteen commenters provided comments related to whether transactional data is useful for making imperfect comparisons.[66] The proposed rule noted, "[f]or FSS vehicles, the clause would be introduced in phases, beginning with a pilot for select products and commoditized services." [67] Following publication of the proposed rule, FAS posted a proposed list of Schedules to be included in the Transactional Data Reporting pilot; the Schedules chosen primarily contained products that generally have standard part numbers, enabling direct comparisons between like items.[68] However, the proposed rule was clear the reporting requirements could expand to all Schedules, including those for services and complex solutions.

Commenters expressed concern that transactional data would eventually be collected and used for goods and services that do not lend themselves to perfect comparisons. Multiple commenters noted it will be difficult, and in some cases impossible, to make one-to-one comparisons for professional services and complex or customizable products, such as laptops. For example, one commenter noted complex service offerings are "priced according to very specific circumstances related to risk, security requirements, geographic area of performance, and the qualifications of the individuals performing the work." [69] Two commenters stated GSA will have difficulty standardizing labor categories in order to make comparisons for service-related transactional data.[70] One commenter suggested the pilot include a professional services Schedule to allow implementation to proceed "in a controlled manner allowing for continuous feedback from contractors and reconsideration of the true intent and usability of the data that GSA is trying to gather." [71] Additionally, one commenter stated GSA is relying on the reported success of the Office Supplies 2 (OS2) contract as validation for transitioning to a horizontal pricing model, which is not a representative sample of the Schedules program.[72]

Multiple commenters stated concerns with how the Government will use prices paid data when conducting a horizontal price analysis. One commenter noted FAR section 15.404–1(b)(2)(ii) allows the "comparison of proposed prices to historical prices paid . . . for the same or similar items" but that paragraph (A) of this FAR section states:

> The prior price must be a valid basis for comparison. If there has been a significant time lapse between the last acquisition and the present one, if the terms and conditions of the acquisition are significantly different, or if the reasonableness of the prior price is uncertain, then the prior price may not be a valid basis for comparison.[73] [74]

Other commenters gave examples of other factors that should be taken into account when making comparisons, such as differing quantities or terms and conditions. For example, one commenter was concerned the data would create a false expectation for the lowest reported prices, as deep discounts can be offered on a one-time based or in response to special promotions, ease of service, volume, or geographic location.[75]

Response: GSA gave consideration as to whether Transactional Data Reporting should be considered for all FSS contracts or only those that include products or services that would allow straightforward comparisons, such as commodities with standard part numbers. GSA agrees transactional data is most useful for price analysis when comparing like items, but disagrees with the notion that the data is not useful when perfect comparisons cannot be made. Namely, the FAR allows comparisons of prices paid for similar items and data for dissimilar items is useful when conducting market research or performing the consumption analysis that underlies the formation of demand management strategies.

Transactional data will assist Government buyers and FSS contracting officers in using the price analysis techniques found in FAR section 15.404–1(b)(2)(ii), as transactional data is necessary to make a comparison of "proposed prices to historical prices paid . . . for the same or similar items." Although paragraph (A) of FAR section FAR section 15.404–1(b)(2)(ii) notes the prior price is not a valid basis of comparison if "there has been a significant time lapse between the last acquisition and the present one, if the terms and conditions of the acquisition are significantly different, or if the reasonableness of the prior price is uncertain . . . ," it does allow for some variance in factors when making comparisons. Furthermore, paragraph (B) of FAR section 15.404–1(b)(2)(ii) not only allows, but requires, a prior price to "be adjusted to account for materially differing terms and conditions, quantities and market and economic factors." In other words, when there has been no significant time lapse, the terms and conditions of an acquisition are similar to previous purchases, and the reasonableness of the prior price is certain, transactional data is valid for comparisons of, if not identical, at least similar items and can be adjusted to account for materially different terms and conditions, quantities, and market and economic factors.

Transactional data will also be instrumental for informing buying decisions and crafting overarching demand management strategies, regardless of whether the data is too dissimilar for price comparisons. For instance, the availability of transactional data will provide buyers visibility into the variables that drive costs, which is key to defining requirements and developing accurate cost estimates. Likewise, category managers will gain insight into the assorted options available for satisfying common requirements, and then use the lessons learned to form demand management strategies that promote the most efficient methods for meeting the Government's needs.

Regarding the differences between the Schedules program and OS2, GSA agrees that the success of the Federal Strategic Sourcing Initiative (FSSI), which includes OS2, was an important factor in GSA's decision to pursue Transactional Data Reporting for the larger Schedules program. While GSA anticipates Transactional Data Reporting will be successful, it recognizes its assumptions should be tested, and therefore opted to begin with a pilot. GSA does not expect this pilot to replicate or exceed the discounts achieved through FSSI—often up to 30 percent lower than the comparable Schedule prices—partly because of the stated differences between the Schedules program and FSSI.

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[65] See Section II.B, Necessity and Value of Transactional Data.

[66] See *e.g.*, ABA Letter, Abt Associates Letter, Allen Letter, ARA Letter, Atkins Letter, CGP Letter, CODSIA Letter, EA Letter, GSA OIG Letter, immixGroup Letter, NDIA Letter, NMFTA Letter, RTI Letter, Shepra Letter, SIA Letter.

[67] See GSAR Case 2013–G504; 80 FR 11619 (Mar. 4, 2015).

[68] GSA proposed five Schedules in a GSA Interact posting following publication of the proposed rule. Those Schedules were 51 V, Hardware Superstore; 58 I, Professional Audio/Video, Telemetry/Tracking, Recording/Reproducing and Signal Data Solutions; 72, Furnishing and Floor Coverings; 73, Food Service, Hospitality, Cleaning Equipment and Supplies, Chemicals and Services; and 75, Office Products.

[69] See NDIA Letter.

[70] See *e.g.*, EA Letter, GSA OIG Letter.

[71] See Abt Letter.

[72] See GSA OIG Letter.

[73] Federal Acquisition Regulation section 15.404–1(b)(2)(ii) (48 CFR 15.404–1(b)(2)(ii)).

[74] See CGP Letter.

[75] See SIA Letter.

In response to the suggestion that a professional services Schedule be included in the pilot before expanding the requirements across the program, GSA has decided to include the Professional Engineering Services SINs from the Professional Services Schedule in the pilot. The pilot will also now include software SINs under Schedule 70, in order to collect data for more complex solutions. The initial pilot will now reach approximately 30 percent of GSA's FSS contracts, including Schedules/SINs covering a wide array of goods and services that account for 43 percent of the Schedules sales volume. This scope will enable GSA to evaluate the effectiveness of Transactional Data Reporting before deciding whether to expand, limit, or discontinue the program.

Finally, GSA recognizes the complexities of employing horizontal price analysis, whether it is through Transactional Data Reporting or other initiatives. For example, the new CPI initiative is built around a tool that identifies contract-level pricing outside a range determined to be acceptable for identical items; vendors whose prices exceed the acceptable range are then notified of their comparative pricing. It is important to reiterate that a range is identified because GSA appreciates the varying circumstances that can contribute to price variation. For CPI, the FSS contracting officer's final determination will take into account non-price elements, such as materially different terms, quantities, and market and economic factors. The GSAM guidance for FSS contracts, which will be viewable on *Acquisition.gov,* instructs FSS contracting officers to make fair and reasonable, not lowest-price-regardless, determinations. Contracting officers placing orders against GSA's Schedules and other multi-agency vehicles will continue to follow the procedures required by the FAR, including a preference for "best value" solutions.[76] Also, GSA is deploying data visualization tools that provide context for the transactional data for a particular good or service.

Public Disclosure of Transactional Data

Thirteen parties provided comments related to public disclosure of transactional data.[77] The proposed rule stated, "GSA also plans to implement an [application programming interface (API)] for buyers to benefit from using transactional data. Through the API, GSA will make this information accessible online for all Government buyers." [78] GSA did not address in the proposed rule whether this data would be shared with the public. Most of the commenters opposed publicly releasing the data and stated GSA must explain how it intends to protect it.

One commenter asked whether GSA will share the transactional data with vendors,[79] while another commenter suggested vendors should have the same access to the data as Government buyers.[80] Ten commenters opposed the release of the data to the public because it will contain proprietary and confidential business information, with most stating vendors will face adverse impacts if the data is shared and requesting GSA explain how it intends to protect the data from unauthorized disclosure.[81] The SBA Office of Advocacy also stated small businesses are concerned about how the data will be protected.[82] Four commenters stated this type of data is protected from disclosure under FOIA, which states the following are exempted: "trade secrets and commercial or financial information obtained from a person and privileged or confidential." [83] [84] One commenter noted the transactional data currently reported under GSA's non-FSS contracts cannot be attributed to a specific vendor.[85] Finally, one vendor stated the rule should provide remedies for vendors in the event of improper disclosure.[86]

Response: Transactional data reported in accordance with this rule will be accessible only by authorized users. GSA intends to share the transactional data with the public to the maximum extent allowable while respecting that some data could be exempt from disclosure. Consequently, a data extract will be created for use by the general public, containing information otherwise releasable under FOIA; [87] details about the public data extract will be released through a forthcoming notice in the **Federal Register**.

Transparency will support a dynamic marketplace by providing vendors with the business intelligence needed to identify customers, determine which products should be included on their contract pricelists, and ascertain whether their prices are competitive. This will be particularly beneficial for small businesses, which often do not have the resources to invest in dedicated business development staff or acquire business intelligence through third-parties.

However, GSA recognizes some information may be protected from public release, which led to the decision to create a public data extract, as opposed to allowing the public the same access as authorized users. The data extract will provide the public a filtered view of the data, including information that is releasable under FOIA, while protecting information that is not.

Finally, GSA is not including remedies in this rule for unauthorized disclosure of data. GSA is taking precautions to prevent unauthorized disclosures of data, but in the event of such an occurrence, GSA will address remedies at that time based on the specific circumstances and in accordance with applicable statutes and regulations.

The Government Already Possesses the Data

Thirteen commenters stated the Government already possesses this data.[88] Several commenters stated the Government should develop systems to collect its own data, with some arguing this will be a difficult task for vendors to undertake. Commenters also suggested alternatives to requiring vendors to report the data.

Transactional data is generated when a transaction is made between a buyer and seller. As such, the parties of the transaction will produce and possess this data. For federal contracting, these parties are the Government ordering agency and the vendor. On the Government side, this data is often found in contract writing systems and financial systems. However, these systems are not shared across agencies; in fact, many agencies use multiple versions of these systems. Moreover, systems that do provide transactional data tend to cover a narrow scope of federal spending. For instance, GSA possesses data for transactions completed through GSA Advantage!®, but it only accounts for about 1 percent of Schedule sales. Hence, no mechanism exists to compile and analyze transactional data from a wide-range of purchases made across the Government.

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[76] Federal Acquisition Regulation section 1.102 (48 CFR 1.102).

[77] See *e.g.,* ABA Letter, Abt Associates Letter, Allen Letter, ARA Letter, CODSIA Letter, CGP Letter, EA Letter, immixGroup Letter, IOPFDA Letter, NDIA Letter, NMFTA Letter, SIA Letter.

[78] See GSAR Case 2013–G504; Docket 2014–0020; Sequence 1 (80 FR 11619 (Mar. 4, 2015)).

[79] See ARA Letter.

[80] See immixGroup Letter.

[81] See *e.g.,* ABA Letter, Abt Associates Letter, Allen Letter, CODSIA Letter, CGP Letter, EA Letter, IOPFDA Letter, NDIA Letter, NMFTA Letter, SBA Letter, SIA Letter.

[82] See SBA Letter.

[83] 5 U.S.C. 552(b)(4)

[84] See *e.g.,* ABA Letter, Allen Letter, EA Letter, NMFTA Letter.

[85] See CGP Letter.

[86] See ABA Letter.

[87] 5 U.S.C. 552.

[88] See *e.g.,* Allen Letter, ARA Letter, Atkins Letter, CODSIA Letter, CGP Letter, Falcone Letter, immixGroup Letter, IOPFDA Letter, Mcdonald Letter, NDIA Letter, NMFTA Letter, RTI Letter, Shepra Letter.

Several commenters objected to GSA requiring vendors to report data that originates from the Government. For example, one commenter stated the Government needs to make investments in automated systems that can provide the data without burdening vendors, and that this rule only delays those eventual investments.[89]

Commenters also stated it will not be easier for vendors to provide the data. One commenter stated many vendors do not keep this type of data as a matter of practice, but for the vendors that do, their reporting systems may not be compatible with GSA's reporting site.[90]

Finally, commenters suggested alternatives to vendor-provided transactional data. Two commenters stated GSA should obtain data from the Federal Procurement Data System (FPDS);[91] two commenters questioned why GSA could not pull data from its GSA eLibrary and GSA Advantage!® sites;[92] two commenters said GSA should rely on data collected from Government purchase card transactions;[93] one commenter proposed GSA use free, price comparisons sites available to the general public;[94] and one commenter stated GSA should already have the ability to obtain the data from other agencies, or otherwise should not be pursuing the rule.[95]

GSA Response: GSA does not have the systems capability to collect transactional data from other agencies. The Initial Regulatory Flexibility Analysis published with the proposed rule included an evaluation of alternatives for obtaining transactional data—internal applications; GSA ordering platforms such as eBuy and GSA Advantage!®; the SmartPay credit card purchase program; and upgrades to the FPDS. GSA previously concluded these options would not provide the breadth of data needed to support the Government's objectives or would be unable to do so in the foreseeable future. Since the publication of the proposed rule, GSA reevaluated those alternatives and reached similar conclusions. Particularly, in regards to relying on purchase card data, doing so would limit the Government to a small, non-representative sample of data that would be ineffective for the broader goals of category management and smarter buying strategies. Although one commenter suggested the Government should increase its purchase card usage in order for purchase card data to be a viable solution, doing so would require numerous regulatory, procedural, and security changes to implement, which could not be accomplished in the near future and therefore would not support the Government's immediate needs.

Additionally, the Government's electronic invoicing initiative[96] was assessed as a potential alternative. However, following meetings regarding electronic invoicing implementation with representatives from the Department of Defense, Department of Energy, Department of Transportation, Department of Treasury, and Department of Veterans Affairs, it was determined these electronic invoicing platforms will not provide a Government-wide transactional data reporting solution in the near term.

Lastly, GSA will consider changes, or even rescind Transactional Data Reporting, as new data systems come online that improve the Government's ability to aggregate and analyze its purchasing data. Also, GSA is exploring ways to synchronize its transactional data intake system with other applications that share common attributes in order to reduce the number of vendor-reported data elements.

Order-Level Competition Ensures Best Value

Nine commenters stated GSA should rely on order-level competition to ensure the Government is receiving the best value.[97] The general sentiment is rather than requiring pricing disclosures or Transactional Data Reporting, GSA should promote order-level competition to meet its pricing objectives. Many of these comments were in response to the following passage from the proposed rule **Federal Register** notice:

> The Government, and other customers in the category to which the government is most typically aligned under the price reductions clause, tend to receive voluntary price reductions from the vendor as a result of general market forces (*e.g.,* intense competition and small profit margins within the IT hardware arena that cause vendors to lower their prices for all customers voluntarily to maintain market share). In other words, prices are reduced under the voluntary provisions of the price reduction clause as a result of market rate pricing changes, not under the mandatory tracking customer provisions. GSA recently analyzed modifications issued between October 1, 2013 and August 4, 2014 under nine of its [Schedules] . . . GSA found that only about 3 percent of the total price reductions received under the price reduction clause were tied to the "tracking customer" feature. The vast majority (approximately 78 percent) came as a result of commercial pricelist adjustments and market rate changes, with the balance for other reasons.[98]

Six of those commenters expressed support for the proposed PRC changes in the context of the general statement that order-level competition is the most effective method for driving down prices.[99]

Response: Competition at the task order level is essential for the Government to ensure it receives the best value, which is one of the reasons GSA is pursuing Transactional Data Reporting. In fact, transactional data has a proven history of driving competition, which is illustrated by the examples shown in Section II.[100] These successes, along with emerging technology, led to the decision to pursue Transactional Data Reporting in lieu of continuing to require CSP and PRC disclosures. Furthermore, this initiative promotes objectives that are not facilitated by order-level competition, such as transparency, demand management, and reducing contract duplication.

Commercial Sales Practices (CSP) Disclosures

Nine parties submitted comments related to the proposed rule's retention of CSP disclosures.[101] While the proposed rule included the removal of the PRC tracking customer provision, it retained CSP disclosures while noting:

> [V]endors would still be subject to the commercial sales disclosure requirements, including the requirement to disclose commercial sales practices when requesting a contract modification for additional items or additional Special Item Numbers. In addition, GSA would maintain the right throughout the life of the FSS contract to ask a vendor for updates to the disclosures made on its commercial sales format (which is used

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[89] See NDIA Letter.

[90] See CODSIA Letter.

[91] See *e.g.,* Atkins Letter, Shepra Letter.

[92] See Atkins Letter, RTI Letter.

[93] See *e.g.,* Allen Letter, Mcdonald Letter.

[94] See CGP Letter.

[95] See NMFTA Letter.

[96] See Office of Management and Budget memorandum M–15–19, "Improving Government Efficiency and Saving Taxpayer Dollars Through Electronic Invoicing", July 17, 2015, available at *https://www.whitehouse.gov/sites/default/files/omb/memoranda/2015/m-15-19.pdf.*

[97] See *e.g.,* ABA Letter, Allen Letter, CODSIA Letter, CGP Letter, EA Letter, immixGroup Letter, IOPFDA Letter, NDIA Letter, RTI Letter.

[98] See GSAR Case 2013–G504; Docket 2014–0020; Sequence 1 (80 FR 11619 (Mar. 4, 2015)).

[99] See *e.g.,* ABA Letter, Allen Letter, CODSIA Letter, immixGroup Letter, NDIA Letter, RTI Letter.

[100] See Section II.B, Necessity and Value of Transactional Data.

[101] See *e.g.,* Abt Associates Letter, ABA Letter, CODSIA Letter, EA Letter, Experian Letter, immixGroup Letter, Johnson & Johnson Letter, RTI Letter, SIA Letter.

to negotiate pricing on FSS vehicles) if and as necessary to ensure that prices remain fair and reasonable in light of changing market conditions.

Nine commenters stated removing the PRC tracking customer feature does not relieve vendors of the burden of tracking commercial pricing, which will still be necessary to provide CSP disclosures.[102] Five commenters stated the proposed rule language would lead to more requests for CSP disclosures.[103] For example, one commenter noted the burden reduction achieved through the PRC changes would be in some cases more than offset by Transactional Data Reporting requirements and increased CSP disclosures.[104]

Response: GSA did not intend for the proposed rule language relating to CSPs to increase disclosures. However, these comments did lead to a reevaluation of the CSP disclosure burden and ultimately the removal of CSP disclosures for FSS vendors subject to the Transactional Data Reporting requirement.

As noted in Section III of this document, GSA also began preparing its routine renewal request for the PRC information collection, identified under OMB Control Number 3090–0235, in the summer of 2015.[105] Since the PRC information collection was last approved in 2012, GSA needed to prepare its information collection renewal request after publishing the Transactional Data Reporting proposed rule. While GSA would have proceeded with a renewal request regardless, the timing did allow for the consideration of the Transactional Data Reporting comments. In particular, GSA agreed with the general industry comment that burdens of the PRC and CSP are related and therefore decided to include CSP disclosure burden estimates with the PRC information collection request (ICR). GSA also opted to change the name of Information Collection 3090–0235 from "Price Reductions Clause" to "Federal Supply Schedule Pricing Disclosures" to more accurately reflect the scope of the information collected.

Following two **Federal Register** notices requesting comments on the FSS Pricing Disclosures ICR,[106] GSA increased its annual burden estimates for GSA FSS contractors, including those who would participate in the Transactional Data Reporting pilot, from $59 million[107] to $102 million.[108] These higher burden projections, coupled with the increased Transactional Data Reporting burden estimates calculated in response to the public comments, were a significant concern and reinforced the need to pair Transactional Data Reporting with other significant forms of burden reductions. Therefore, GSA is removing CSP disclosures in addition to the PRC tracking customer provision for FSS vendors subject to the new Transactional Data Reporting clause, resulting in an average annual burden reduction for FSS pilot contractors of approximately $32 million.[109] Additionally, implementing the FSS pilot without the existing CSP and PRC requirements lowers the Government's burden by about $3 million a year.[110]

Transactional Data Reporting negates the need for CSP disclosures when used in conjunction with automated commercial data sources, new data analytic tools, and improved price analysis policy. As discussed in Section IV of this document,[111] GSA is releasing new GSAM guidance, which will be viewable on *Acquisition.gov,* that provides instructions to FSS contracting officers on how to evaluate offers and establish negotiating objectives without relying on CSP disclosures. For example, the new guidance provides the following order of preference for information:

1. Use data that is readily available, in accordance with FAR 15.404–1(b)(2)(ii),[112] including prices paid information on contracts for the same or similar items; contract-level prices on other FSS contracts or Governmentwide contracts for the same or similar items, and commercial data sources providing publicly available pricing information.

2. Perform market research to compare prices for the same or similar items in accordance with FAR 15.404–1(b)(2)(vi).[113]

3. Request additional pricing information such as "data other than certified cost or pricing data" (as defined at FAR 2.101[114]) from the offeror in accordance with FAR 15.404–1(b)(2)(vii)[115] when the offered prices cannot be determined to be fair and reasonable based on the data found from other sources.

Small Business Impacts

Multiple commenters addressed small businesses in other comments, but six commenters stated there are certain aspects of the rule are especially impactful on small business.[116] In the proposed rule, GSA did not create separate requirements for small businesses or other classes of vendors. Additionally, the burden analysis separated FSS vendors into categories based on Schedule sales volume but did not calculate separate burden estimates for small or other-than-small businesses.

Three commenters noted that this rule will make it more difficult for small businesses to compete against other-than-small businesses in the federal marketplace,[117] citing an overemphasis on pricing over value-added services. Two of those commenters stated GSA did not adequately address small business impacts.[118] Additionally, four commenters expressed concern over small businesses' ability to absorb the costs associated with the new reporting requirements, which creates a barrier to entry into the federal marketplace.[119] Lastly, one commenter stated the Initial Regulatory Flexibility Analysis did not provide a clear understanding of the legal framework for requiring Transactional Data Reporting.[120]

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[102] See *e.g.*, Abt Associates Letter, ABA Letter, CODSIA Letter, EA Letter, Experian Letter, immixGroup Letter, Johnson & Johnson Letter, RTI Letter, SIA Letter.

[103] See *e.g.*, Abt Associates Letter, ABA Letter, CODSIA Letter, EA Letter, SIA Letter.

[104] See CODSIA Letter.

[105] See Section III.B, Alternatives Analysis.

[106] See 80 FR 72060 (Nov. 18, 2015) and 81 FR 21346 (Apr. 11, 2016).

[107] The 2012 information collection did not provide a cost burden estimate, but if the same hourly rate ($68) was applied to the 2012 time burden, the 2012 cost burden would have been $59,086,560.

[108] The annual public reporting burden for the CSP and PRC, excluding FSS vendors participating in the Transactional Data Reporting pilot, is $57.66 million. If FSS pilot vendors were still subject to the CSP and PRC reporting requirements, the total annual public reporting burden would be $101.69 million. The FSS pilot vendors' share of the total CSP and PRC reporting burden is based upon their share of the GSA FSS fiscal year 2015 sales volume, 43.2 percent. The annual $44.03 million reporting burden reduction attributed to this rule is 43.2 percent of the $101.69 million annual reporting burden if it were applied to the entire GSA FSS program. More information about Information Collection 3090–0235 can be found at *http://www.reginfo.gov/public* by searching "ICR" for "3090–0235".

[109] $32 million does not include costs for non-FSS contracts. It is the result of the FSS burden of the initial pilot implementation ($12.41 million), minus the share of the combined CSP and PRC burden allocated to the FSS pilot vendors ($44.03 million). The total CSP and PRC burden from Information Collection 3090–0235, if it were applied to all GSA FSS vendors, including those participating in the Transactional Data Reporting pilot, would be $101.69 million. The share of that burden allocated to the FSS pilot vendors ($44.03 million) is based on the percentage of the overall FY15 FSS sales accounted for by the FSS pilot vendors (43.2 percent).

[110] $3 million is the result of the Government's annual burden for this rule ($2.34 million) minus the share of the combined CSP and PRC burden for the Government allocated to the FSS pilot contracts ($5.58 million).

[111] See Section IV.D, Procedures.

[112] Federal Acquisition Regulation section 15.404–1(b)(2)(ii) (48 CFR 15.404–1(b)(2)(ii)).

[113] Federal Acquisition Regulation section 15.404–1(b)(2)(iv) (48 CFR 15.404–1(b)(2)(iv)).

[114] Federal Acquisition Regulation 2.101 (48 CFR 2.101).

[115] Federal Acquisition Regulation section 15.401–1(b)(2)(vii) (48 CFR 15.404–1(b)(2)(vii)).

[116] See *e.g.*, ABA Letter, CGP Letter, Falcone Letter, Insite.rr.com Letter, RTI Letter, SBA Letter.

[117] See *e.g.*, ABA Letter, CGP Letter, SBA Letter.

[118] See *e.g.*, ABA Letter, SBA Letter.

Response: GSA was especially mindful of small business concerns when forming this rule and believes small businesses will benefit significantly by no longer being subjected to the complex CSP and PRC pricing disclosure requirements. Moreover, under the Transactional Data Reporting, burden is tied to sales volume, which will also benefit small businesses, as they hold 80 percent of the total contracts and account for 39 percent of sales.[121] Unlike the new data reporting requirements, the current CSP and PRC disclosure requirements are constant, meaning vendors, especially those with a higher number of FSS contract offerings, must bear the burden even if they have little to no sales through their FSS contracts. Thus, small businesses are disproportionately affected by the current reporting requirements because they account for the bulk of lower volume contracts.

GSA intends to share transactional data to the maximum extent allowable to promote transparency and competition while respecting that some data could be exempt from disclosure. The data will serve as valuable market intelligence for vendors to use for crafting more efficient, targeted business development strategies that incur lower administrative costs. This will be particularly beneficial for small businesses, which often do not have the resources to invest in dedicated business development staff or acquire business intelligence through third-parties.

Nevertheless, GSA will be mindful of Transactional Data Reporting's small business impacts. The initiative is being phased in on a pilot basis. GSA's Senior Procurement Executive will regularly evaluate progress against metrics, including small business participation, in consultation with the Administrator for Federal Procurement Policy and other interested stakeholders to determine whether to expand, limit, or discontinue the program. No expansion of the pilot or action to make Transactional Data Reporting a permanent fixture on the Schedules will occur prior to the careful evaluation of at least one year of experience with the pilot.

With respect to the burden analysis, GSA did not differentiate between small businesses and other-than-small businesses in its burden estimates because Transactional Data Reporting imposes a progressive burden—one that increases with a vendor's sales volume. Namely, monthly reporting time will increase with a vendor's applicable sales volume, as vendors with lower to no reportable sales will spend little time on monthly reporting, while those businesses with more reportable sales will face a higher reporting burden. Likewise, setup costs will be a major driver of the new reporting burden, but vendors with little to no activity on their FSS contracts will likely forgo investments in new reporting systems because the reporting burden will not be significantly more than that of the current quarterly sales reporting requirements.

Finally, in regards to the legal framework of the new system, GSA will be implementing the Transactional Data Reporting clauses through bilateral modifications on existing contracts, meaning vendors must agree to the changes before GSA can insert a new clause in a contract. New contracts awarded under the pilot Schedules/SINs or future Governmentwide IDIQ vehicles will include the new Transactional Data Reporting clauses, but vendors will have an opportunity to view the requirements before agreeing to a contract. For the Schedules, GSA is instituting this program to meet its obligations under 41 U.S.C. 152(3)(b), which states that orders and contracts awarded under the FSS program must result in "the lowest overall cost alternative to meet the needs of the Federal Government."

Transactional Data Reporting Will Have Adverse Impacts for the Government

Six commenters stated Transactional Data Reporting will lead to a counterproductive fixation on lower prices.[122] Two commenters stated horizontal price analysis will obscure differences in terms and conditions and adversely impact the Government's ability to achieve the best value.[123] Three commenters also said there is a significant risk of horizontal pricing forcing quality providers to leave the FSS program because of an expectation of untenable low prices.[124] Another commenter stated price transparency will provide a disincentive for offering spot discounts because doing so will create a permanent expectation for those prices.[125] Finally, one commenter stated this rule may cause prices to increase because costs to comply with Transactional Data Reporting will outweigh the potential gains achieved through horizontal pricing.[126]

Response: Horizontal pricing models that leverage transactional data have a proven track record of lowering prices. As shown in Section II of this document,[127] GSA has successfully instituted horizontal pricing models, resulting in savings of nearly 30 percent on Office Supplies 3 (OS3), 26 percent on FSSI Wireless, and 34 percent on COMSATCOM. These are savings that taxpayers rightfully deserve.

FSS contracting officers will be instructed to evaluate the data in the context of each offer, taking into account not only cost and quantity discounts, but desired terms and conditions, unique attributes, socio-economic considerations, and other relevant information. Contracting officers will further be encouraged to discuss with the offeror perceived variances between offered prices, transactional data, and existing contract-level prices, in order to evaluate whether other attributes (*e.g.,* superior warranties, quantity discounts) justify awarding higher prices.

More importantly, transactional data provides benefits beyond better pricing. For instance, it supports the key category management principles of optimizing existing contract vehicles and reducing contract duplication.[128] With transactional data, the Government can analyze its consumption patterns, evaluate and compare purchasing channels, and identify best-in-class solutions. Thereafter, the Government can leverage its buying power and demand management strategies to achieve taxpayer savings as it concentrates its purchases through fewer channels, while vendors realize lower administrative costs. Facilitating the development of demand management strategies is also a significant benefit. As illustrated by GSA's Domestic Delivery Services 2 (DDS2), transactional data provided valuable insight into how shipping needs were met and helped the Government change its consumption behavior by foregoing unnecessary express air shipments in favor of less expensive ground shipments. By Fiscal Year 2015, air shipments shrank from 90 percent to 60 percent of revenue and 46 percent of total shipments, while ground shipments grew to 40 percent of revenue and 54 percent of total shipments.

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[119] See *e.g.,* ABA Letter, Falcone Letter, Insite.rr.com Letter, RTI Letter.

[120] See SBA Letter.

[121] Based on fiscal year 2015 Federal Supply Schedule contract data.

[122] See *e.g.,* ABA Letter, Allen Letter, CGP Letter, CODSIA Letter, Experian Letter, SIA Letter.

[123] See *e.g.,* EA Letter, CGP Letter.

[124] See *e.g.,* Experian Letter, SIA Letter, CGP Letter.

[125] See Allen Letter.

[126] See ABA Letter.

[127] See Section II.B, Necessity and Value of Transactional Data.

[128] See "Government-wide Category Management, Guidance Document, Version 1.0," Office of Management Budget, May 2015, available at *https://hallways.cap.gsa.gov/information/Gov-wide_CM_Guidance_V1.pdf.*

Lastly, GSA recognizes the costs for compliance with the Transactional Data Reporting requirements make it necessary to alleviate the burden of other compliance requirements. Therefore, this rule removes CSP disclosures and the PRC tracking customer provision for FSS vendors subject to the new Transactional Data Reporting clause, resulting in an average annual burden reduction of approximately $32 million for FSS pilot vendors.[129] Additionally, implementing the FSS pilot without the existing CSP and PRC requirements lowers the Government's burden by about $3 million a year.[130] These changes, coupled with transactional data's virtues, ensure this rule will benefit the Government and lead to savings for the American taxpayer.

Business Liability Risk

Four parties submitted comments relating to increased business liability risks.[131] Two commenters stated the transactional data vendors submit would increase the amount of information that can be audited, and thereby, more audits, investigations, lawsuits, and other punitive actions.[132] The other two commenters predicted increased allegations of fraud under the False Claims Act stemming from data inaccuracies.

Response: False Claims arise when a person "knowingly" deceives the Government.[133] As such, GSA does not anticipate increased False Claims actions because there is no expectation of an increase in vendors "knowingly" deceiving the Government. Moreover, the new Transactional Data Reporting site will allow vendors more leeway to fix errors than the current 72A Reporting System. While sales adjustments submitted through the 72A system must be approved by the assigned Industrial Operations Analyst (IOA), vendors will be able to submit data corrections through the new site on their own, although IOAs will be notified of corrections over a certain dollar threshold.

Transactional Data Reporting will also provide greater ease of compliance with the removal of CSP disclosures and the PRC tracking customer provision. Reporting transactional data is based upon data used to generate a standard invoice. On the other hand, navigating the PRC and CSP requirements is complex because they require industry partners to track their GSA pricing relative to all of their commercial customers, and monitor and control all of their commercial sale transactions.

Government Usage of Transactional Data

Four parties submitted comments related to the Government's procedures for using transactional data.[134] One commenter stated there will be risk to the contracting officer and asked what will happen if they do not succeed in obtaining the lowest price.[135] Another commenter asked how the Government will account for jurisdictional and geographic pricing variances; if there will be a mechanism to correct erroneous data; and how does GSA plan to analyze data that can rapidly fluctuate.[136] Two commenters asked what tools and training will be available to ensure price is not the sole award criteria.[137] Finally, one commenter stated this rule will lead to GSA contracting officers seeking to continually renegotiate Schedule contracts.[138]

Response: GSA is creating procedures and training to address the use of transactional data, as outlined in Section IV.[139] GSA will not mandate contracting officers to receive the lowest reported price when conducting best value procurements. In these forums, consideration will be given to pricing variances caused by factors such as differing terms and conditions, places of performance, and quantity.

GSA will offer training and guidance for category managers and contracting officers. The Category Management Leadership Council has released a guidance document for category managers. The document provides "guidance for the governance, management and operations of category management, taking into consideration the inherent complexities of a Federal-wide initiative." [140] It does not dictate operational contracting decisions, nor does it supersede the FAR, which states a preference for "best value" solutions.[141] GSA is also updating relevant courseware on the Federal Acquisition Institute (FAI) and Defense Acquisition University (DAU) portals to educate both customers and GSA contracting officers on how to use the data. Similarly, the courseware on how to use the FSS program and other non-FSS GWACs and multi-agency IDIQs will be updated to educate customers on the new requirements and how they can use the data collected to buy smarter. The external courseware will also highlight the additional value transactional data offers to GSA's FSS and non-FSS contracting programs and emphasize it must be viewed in the context of each procurement, taking into account desired terms and conditions, performance levels, past customer satisfaction, and other relevant information.

To address erroneous data, the new Transactional Data Reporting site will allow vendors more leeway to correct mistakes than the current 72A Reporting System. While sales adjustments submitted through the 72A system must be approved by the assigned IOA, vendors will be able to submit data corrections through the new site on their own, although IOAs will be notified of corrections over a certain dollar threshold.

As for evaluating rapidly changing data, GSA opted to require monthly, rather than quarterly, data reporting to improve the recency of the data. However, GSA acknowledges prices may fluctuate for reasons including, but not limited to, changing and cyclical demand. This is why, among other reasons such as varying attributes, that GSA does not have an expectation to always receive the lowest reported price.

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[129] $32 million does not include costs for non-FSS contracts. It is the result of the FSS burden of the initial pilot implementation ($12.41 million), minus the share of the combined CSP and PRC burden allocated to the FSS pilot vendors ($44.03 million). The total CSP and PRC burden from Information Collection 3090–0235, if it were applied to all GSA FSS vendors, including those participating in the Transactional Data Reporting pilot, would be $101.69 million. The share of that burden allocated to the FSS pilot vendors ($44.03 million) is based on the percentage of the overall FY15 FSS sales accounted for by the FSS pilot vendors (43.2 percent).

[130] $3 million is the result of the Government's annual burden for this rule ($2.34 million) minus the share of the combined CSP and PRC burden for the Government allocated to the FSS pilot contracts ($5.58 million).

[131] See *e.g.,* Allen Letter, CODSIA Letter, CGP Letter, EA Letter.

[132] See Allen Letter, EA Letter.

[133] 31 U.S.C 3729.

[134] See *e.g.,* ARA Letter, EA Letter, Experian Letter, immixGroup Letter.

[135] See immixGroup Letter.

[136] See ARA Letter.

[137] See ARA Letter, Experian Letter.

[138] See EA Letter.

[139] See Section IV.D, Procedures.

[140] See "Government-wide Category Management, Guidance Document, Version 1.0," Office of Management Budget, May 2015, available at *https://hallways.cap.gsa.gov/information/Gov-wide_CM_Guidance_V1.pdf.*

[141] Federal Acquisition Regulation section 1.102 (48 CFR 1.102).

Finally, GSA does not intend to continually renegotiate all prices based on transactional data; doing so would be an administrative burden for all parties involved. However, GSA is beginning to employ automated analysis techniques for its contract-level prices to reduce variability. For example, the new Formatted Product Tool (FPT) identifies pricing outside a range determined to be acceptable for identical items; vendors whose prices exceed the acceptable range are then notified of their comparative pricing. Currently, this initiative applies only to products, while services will be addressed at a later date. However, whether it be the FPT or other tools, it is important to note GSA intends to view pricing in a range, so renegotiations will not be triggered merely because a vendor does not meet the lowest-reported price.

The Price Reductions Clause Tracking Customer Provision Should Not Be Eliminated

Two commenters stated GSA should not pair Transactional Data Reporting with the removal of the PRC tracking customer provision. The first commenter stated prices paid by the Government do not necessarily equate to the best price,[142] while the second commenter stated the proposed rule failed to justify removing the tracking customer feature in favor of Transactional Data Reporting, noting "there is no price protection provision built into the alternative language of the proposed rule." [143] Both commenters stated removing the PRC would sever the Schedules program's link to the commercial marketplace.

GSA currently establishes price reasonableness on its FSS contracts by comparing a contractor's prices and price-related terms and conditions with those offered to their other customers. Through analysis and negotiations, GSA establishes a favorable pricing relationship in comparison to one of the contractor's customers or category of customers. Contractors are then required, under the PRC, to monitor their pricing over the life of the contract and provide the Government with the same price reductions they give to the class of commercial customers upon which the original contract award was predicated.[144] In addition to the tracking customer requirement, the PRC allows vendors to voluntarily reduce prices to the Government and for the Government to request a price reduction at any time during the contract period, such as where market analysis indicates that lower prices are being offered or paid for the same items under similar conditions.

In the proposed rule, GSA moved to couple the FSS Transactional Data Reporting clause with a new alternate version of the PRC that did not include the tracking customer provision. This new alternate PRC would only retain the Government's right to request price reductions and the contractor's right to offer them. The rationale for this idea was explained in the proposed rule **Federal Register** notice:

> GSA believes the collection and use of transactional data may be a more efficient and effective way for driving price reductions on FSS buys than through use of the tracking customer mechanism. In addition to avoiding the challenges associated with the tracking customer mechanism described above, the transactional data reporting clause would allow for greater reliance on horizontal pricing in the FSS program so that GSA and its customers can easily evaluate the relative competitiveness of prices between FSS vendors. Moreover, the transactional data reporting clause, if used as an alternative to tracking customer mechanism, could significantly reduce contractor burden. The Chief Acquisition Officers Council recently conducted an Open Dialogue through an online platform on improving how to do business with the Federal Government. Contractors pointed to the price reductions clause as one of the most complicated and burdensome requirements in Federal contracting, and GSA's own estimates suggest FSS contractors spend over 860,000 hours a year (at a cost of approximately $58.5 million) on compliance with this clause.[145]

One commenter acknowledged the benefits of transactional data to impact pricing but stated the new Transactional Data Reporting clause will not require vendors to offer price reductions based upon transactional data, in contrast to the PRC, which has protections to require FSS vendors to offer price reductions following a triggering event. In the proposed rule, GSA also stated it found only 3 percent of price reduction modifications were tied to the tracking customer feature, while approximately 78 percent of those modifications were voluntary, resulting from commercial pricelist adjustments and market rate changes.[146] The commenter responded to these claims by arguing many of the voluntary price reduction modifications may have been requested in order to comply with the PRC, as well as noting that GSA did not quantify the savings resulting from the modifications tied to the tracking customer feature. Additionally, the commenter stated a more comprehensive analysis of the PRC's values and benefits is needed before acting to remove the tracking customer feature. Finally, the commenter questioned the methodology used to form the PRC burden estimates included in the 2012 information collection request (ICR), which relied upon a survey conducted by The Coalition for Government Procurement. GSA included the 2012 ICR burden estimates in its calculation that resulted in a net burden reduction, but the commenter stated the underlying survey did not use a representative sample as it included responses from less than 1 percent of FSS contractors.[147]

Response: Pricing disclosures, such as the CSP and PRC, have served as the bedrock of the Schedules program pricing approach at least as far back as the 1980s. With limited other means of data collection available, they offered a way to ensure fair and reasonable pricing through the life of a contract with the goal of achieving most favored customer pricing. However, changes in the federal marketplace have eroded the effectiveness of these practices over time. Of particular note are the explosive growth of services, increase in share of contracts held by resellers rather than manufacturers, and establishment of elaborate structures by contractors seeking to limit potential liability. Moreover, due to the various exceptions included in the PRC, the tracking customer feature ties pricing for reductions to sales of single items and plays little role in blanket purchase agreement and order purchases reflecting volume sales. Further, many products sold under the FSS program are commercial-off-the-shelf (COTS) products or other commercial items for which the Government is not a market driver.

Using transactional data will be a more efficient and effective way for driving price reductions. In addition to avoiding the challenges associated with the tracking customer mechanism described above, the transactional data reporting clause would allow for greater reliance on horizontal pricing in the FSS program so that GSA and its customers can easily evaluate the relative competitiveness of prices between FSS vendors. Although this rule removes the PRC's price protection provision, order-level competition and transparency will proactively achieve the same objective without relying on retroactive enforcement. Companies seeking to win Schedules business will offer discounts or better value than their competitors. Currently, the lack of transparency encourages vendors to offer inconsistent pricing to federal buyers. In contrast, the availability of transactional data will mean all federal buyers may be rewarded by the success of a single buyer. In turn, competing companies will have a better understanding of what it takes to win federal business and will therefore submit stronger offers. GSA's successful use of transactional data to date has shown the benefits of horizontal price analysis will outweigh the value of the PRC. While the Government often recoups millions of dollars through PRC enforcement, the American taxpayer may save billions of dollars as the Government leverages transactional data.

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[142] See POGO Letter.

[143] See GSA OIG Letter.

[144] General Services Administration Acquisition Regulation clause 552.238–75 (48 CFR 552.238–75).

[145] See GSAR Case 2013–G504; (80 FR 11619 (Mar. 4, 2015)).

[146] *Id.*

[147] See GSA OIG Letter.

However, initiating Transactional Data Reporting in conjunction with the existing PRC and CSP disclosure requirements would be unduly burdensome and likely counterproductive. For example, performance under the Office Supplies 3 (OS3) vehicle began in Fiscal Year 2015. Like its predecessor, OS2, OS3 relies on transactional data and horizontal pricing techniques to drive savings. But unlike the Schedules-based OS2, OS3 is a standalone IDIQ that does not include the traditional FSS CSP and PRC requirements. As such, OS3's pricing is 17 percent lower than its predecessor's prices.[148] This reinforces the case for coupling Transactional Data Reporting with the removal of the CSP and PRC requirements, which will provide a $32 million a year burden reduction for FSS pilot vendors.[149]

To preserve its link to the commercial marketplace, GSA is posting new GSAM guidance for FSS contracting officers to use when relying on transactional data in lieu of CSP disclosures and the basis of award enforced by the PRC. The new guidance will include an order of preference for that includes prices paid information on contracts for the same or similar items; contract-level prices on other FSS contracts or Government-wide contracts for the same or similar items; and commercial data sources providing publicly available pricing information. FSS contracting officers will also still have the ability to request additional pricing information such as "data other than certified cost or pricing data" (as defined at FAR 2.101 [150]) in accordance with FAR 15.404–1(b)(2)(vii) [151] when the offered prices cannot be determined to be fair and reasonable based on the data found from other sources.

With respect to the 2012 survey sample size, GSA acknowledges this concern but did not base its projections solely on the survey. The PRC projections were recently reevaluated for the renewal of the related information collection request and increased from $59 million [152] to $74 million, if the PRC were to apply to all GSA FSS contracts.[153]

Reporting Frequency

Two parties submitted comments related to the proposed reporting frequency. GSA proposed for non-FSS vendors subject to the rule to report sales monthly within 15 calendar days after the end of the calendar month and to remit any Contract Access Fee (CAF) due within 15 calendar days after the end of the calendar month. For FSS vendors, GSA proposed that they report sales monthly within 15 calendar days after the end of the calendar month and to remit any Industrial Funding Fee (IFF) due within 30 calendar days after the end of each quarter.

The first commenter stated the proposed 15-day reporting window did not provide vendors enough time to prepare and review the data to be reported. This commenter also stated the inconsistency between monthly reporting and quarterly payments may be unnecessarily confusing for vendors.[154] The second commenter stated GSA should reconsider the frequency, as monthly reporting is excessive, and particularly duplicative for service-providers whose prices may not change over the course of year; the commenter suggested having professional services vendors only report once or twice a year.[155]

Response: GSA considered the comment relating to the 15-day reporting window and agrees it is insufficient. Therefore, the new reporting clauses require vendors to report sales within 30 calendar days after the end of each calendar month.

With respect to monthly reporting versus quarterly payment, GSA opted to not require monthly payment for the FSS clause (GSAR 552.238–74 Alternate I) because doing so would be disproportionately harmful for small businesses, many of whom remit fees based on accrued billings before they actually receive payments from their Government customers. Payment frequency is not addressed in the non-FSS clause (GSAR 552.216–75) but vendors will have at least 30 days after the last day of the month to remit fees, as applicable.

Finally, GSA chose not to require less frequent reporting because doing so would lessen the impact of transactional data, which becomes less actionable as time passes.

Recommended Changes to Regulatory Text

Two commenters provided suggested changes to GSA's regulatory text. The first commenter stated GSA must update GSAR Figure 515.4–2 [156] and GSAR section 538.272 [157] to address the proposed PRC changes. This commenter also stated the sections of the basic PRC that were retained in the new PRC Alternate II, which allow the Government to seek price reductions and a contractor to offer them, are not necessary because both parties would normally have these rights during negotiations.[158]

The second commenter suggested two changes to the regulatory text. The first change would replace "Offerors must include the CAF in their prices" with "The CAF will be charged as a separate and distinct line item on every order" in paragraph (c) of the proposed non-FSS Transactional Data Reporting clause, 552.216–75. The second suggestion was to insert "or services" in the description of contract sales "and sales made to other contractors authorized under FAR part 51 or the FAR part 51 deviation authorities" in the last sentence of paragraph (a)(1) of the proposed FSS Transactional Data Reporting clause, 552.238–74 Alternate 1.[159]

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[148] GSA analyzed pricing awarded through August 31, 2015 in its analysis.

[149] $32 million does not include costs for non-FSS contracts. It is the result of the FSS burden of the initial pilot implementation ($12.41 million), minus the share of the combined CSP and PRC burden allocated to the FSS pilot vendors ($44.03 million). The total CSP and PRC burden from Information Collection 3090–0235, if it were applied to all GSA FSS vendors, including those participating in the Transactional Data Reporting pilot, would be $101.69 million. The share of that burden allocated to the FSS pilot vendors ($44.03 million) is based on the percentage of the overall FY15 FSS sales accounted for by the FSS pilot vendors (43.2 percent).

[150] Federal Acquisition Regulation section 2.101 (48 CFR 2.101).

[151] Federal Acquisition Regulation section 15.401–1(b)(2)(vii) (48 CFR 15.404–1(b)(2)(vii)).

[152] The 2012 information collection did not provide a cost burden estimate, but if the same hourly rate ($68) was applied to the 2012 time burden, the 2012 cost burden would have been $59,086,560.

[153] The CSP and PRC burden estimates are from Information Collection 3090–0235, FSS Pricing Disclosures. The total annual public reporting burden for the CSP and PRC, excluding FSS vendors participating in the Transactional Data Reporting pilot, is $57.66 million, $41.73 million of which is attributed to the PRC. If FSS pilot vendors were still subject to the CSP and PRC reporting requirements, the total annual public reporting burden would be $101.69 million, of which $73.73 million would be attributed to the PRC. The FSS pilot vendors' share of the total CSP and PRC reporting burden is based upon their share of the GSA FSS fiscal year 2015 sales volume, 43.2 percent. The annual $44.03 million reporting burden reduction attributed to this rule is 43.2 percent of the $101.69 million annual reporting burden if it were applied to the entire GSA FSS program. More information about Information Collection 3090–0235 can be found at *http://www.reginfo.gov/public* by searching "ICR" for "3090–0235".

[154] See ABA Letter.

[155] See Abt Letter.

[156] General Services Administration Acquisition Regulation Figure 515.4–2 (48 CFR 515.4–2).

[157] General Services Administration Acquisition Regulation section 538.272 (48 CFR 538.272).

[158] See ABA Letter.

Response: GSA concurs with the suggested changes for GSAR Figure 515.4–2 and GSAR section 538.272 and is subsequently amending those sections. The prescription for Figure 515.4–2 has been revised to only be required when the basic clause 552.238–74 Industrial Funding Fee and Sales Reporting is in solicitations and contracts. Additionally, GSAR section 538.272 has been changed to only apply to the basic PRC and Alternate I; the new PRC Alternate II, created by this rule, is not included.

As for the suggested updates to GSAR clause 552.216–75, GSA no longer instructs offerors to include the CAF in their prices because many non-FSS programs include the CAF as a separate line item. However, GSA wants its non-FSS contract programs to have the flexibility to structure the CAF to meet their business needs, so it is instead choosing to provide the contractor with relevant instructions within 60 days of award or inclusion of this clause in the contract.

With respect to the suggestions to paragraph (a)(1) for GSAR clause 552.238–74 Alternate I, GSA has removed the definition for "contract sale" and instead included similar language in paragraph (c)(3).

"Contract sale" was removed from the definitions because this clause requires contractors to report transactional data, not "contract sales" as required by the basic version of GSAR clause 552.238–74.

Transactional Data Reporting on Cost Reimbursable Contracts

Comment: Two commenters stated the rule should exclude cost reimbursable contracts.[160] One commenter stated cost-type contracts should be excluded because the pricing will be based on Defense Contract Audit Agency pricing practices. The other commenter stated collecting data on these contracts will not be useful because the cost elements will be unique and the contracting officer already receives the information upfront to make pricing determinations.[161]

Response: GSA will only collect data on cost reimbursable contracts awarded under contracts subject to clause 552.216–75, as cost-type contracts are not permitted under the Schedules program. GSA recognizes cost reimbursable data may not have the same utility as data collected under time and materials and labor hour orders, but there are still numerous benefits. For example, the Government can use this data to analyze its consumption patterns, evaluate and compare purchasing channels, and identify best-in-class solutions. Thereafter, the Government can leverage its buying power and demand management strategies to achieve taxpayer savings as it concentrates its purchases through fewer channels, while vendors realize lower administrative costs.

Other Comments

The following are comments submitted by a single party and GSA's corresponding responses.

Comment: A commenter stated vendors "should pay back the overcharge part of the time, back to the taxpayers with a hefty fine included."[162]

Response: GSA does not concur because the comment is outside the scope of this rule.

Comment: GSA cannot claim the Multiple Award Schedule Advisory Panel recommendation as a mandate for this rule because panel members expressed concern that price comparison tools would have to provide accurate comparisons.[163]

Response: The Panel reference in the proposed rule **Federal Register** notice referred to a recommendation to remove the PRC "as the GSA Administrator implements recommendations for competition and price transparency at the Schedule contract level and the order level."

Comment: One commenter stated this rule is inconsistent with the Federal Acquisition Streamlining Act of 1994 (FASA)[164] and the subsequent procedures in FAR Part 12, which aims to "establish policies more closely resembling those of the commercial marketplace."[165]

Response: GSA's intention is to further align itself with commercial buying practices. Horizontal price analysis is a common technique used by commercial firms and individual citizens, and one that GSA plans to further leverage through the use of transactional data. To the contrary, the removal of CSP disclosures and the PRC tracking customer provision, which both predate FASA, are an attempt, in conjunction with horizontal pricing techniques, to harmonize GSA policies with the FAR and commercial buying practices.

Comment: One commenter expressed concern that GSA is planning to eliminate the Schedules program and will require vendors to provide transactional data from commercial accounts.[166]

Response: GSA is not planning on eliminating the Schedules program and will not require vendors to provide transactional data from commercial accounts.

Comment: GSA should slow down implementation of the rule to spend more time working with industry on its impacts.[167]

Response: GSA has already undertaken a lengthy process to implement Transactional Data Reporting, starting with the rulemaking process that included a **Federal Register** notice of proposed rulemaking and a public meeting, and continuing with a pilot that will allow GSA to evaluate the program's effectiveness and collect stakeholder feedback as it is implemented.

Comment: One commenter stated details regarding the pilot's evaluation metrics and expansion are undefined.[168]

Response: GSA will use evaluation metrics including, but not be limited to, changes in price, sales volume, and small business participation, as well as macro use of transactional data by category managers and teams to create smarter buying strategies such as consumption policies. GSA's Senior Procurement Executive will regularly evaluate progress against these metrics in consultation with the Administrator for Federal Procurement Policy and other interested stakeholders to determine whether to expand, limit, or discontinue the program. No expansion of the pilot or action to make Transactional Data Reporting a permanent fixture on the Schedules will occur prior to the careful evaluation of at least one year of experience with the pilot.

Comment: The proposed rule does not account for the resources expended by vendors and Government to implement the requirements in the event GSA chooses to abandon the pilot and revert back to its current practices.[169]

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[159] See deMers Letter.

[160] See *e.g.*, CGP Letter, RTI Letter.

[161] See RTI Letter.

[162] See Lynch Letter.

[163] See Allen Letter.

[164] Pubic Law 103–355.

[165] Federal Acquisition Regulation section 12.000 (48 CFR 12.000).

[166] See IOPFDA Letter.

[167] *Ibid.*

[168] See GSA OIG Letter.

Response: GSA anticipates Transactional Data Reporting will be successful but recognizes its assumptions should be tested, hence its preference for a pilot. CSP disclosures and the basic versions of the PRC and FSS sales reporting clause (552.238–74) are being retained during the course of the pilot and will be available for use if GSA chooses not to continue Transactional Data Reporting. However, the agency is continually improving its tools and procedures and may opt to retain facets of this rule, or rely on new tools, if either proves to be more effective than the current pricing disclosure practices. Impacts on industry partners will be given significant consideration as these decisions are made.

Comment: Transactional Data Reporting should exclude blanket purchase agreements (BPAs) because there will likely be quantity discounts offered and fixed price-type contracts because the prices are not relevant as the terms are determined based on unique agency requirements.[170]

Response: GSA is collecting contract and BPA numbers in order to tie the transactional data to records in the Federal Procurement Data System (FPDS). Doing so will not only make the transactional data more useful, but will also reduce the number of data elements vendors need to report to GSA. As FPDS is upgraded, GSA intends to evaluate whether any of the data elements currently included in the new reporting clauses can be excluded. For BPAs in particular, policy and training will instruct contracting officers to evaluate the data in the context of each offer, taking into account desired terms and conditions, quantity discounts, unique attributes, socio-economic considerations, and other relevant information.

Finally, GSA recognizes fixed price data will have limited value compared to data reported for other contract types, but there are still numerous benefits. The Government can use fixed price data to analyze its consumption patterns, evaluate and compare purchasing channels, and identify best-in-class solutions. Thereafter, the Government can leverage its buying power and demand management strategies to achieve taxpayer savings as it concentrates its purchases through fewer channels, while vendors realize lower administrative costs. Fixed price data will also be useful for market research; for example, the data will be especially useful when combined with information from the eBuy statement of work (SOW) library.

Comment: The rule should impose limits on the timeframe for which data is reported and used by contracting officers for price analysis. The commenter provided the following example: "[I]f a company currently has a contract with a 10-year period of performance and is in contract year 4, the contractor should not be required to report prices paid from inception-to-date. In essence, the rule should not be retroactive." [171]

Response: Vendors are required to report data based on invoices issued or payments received against applicable invoices during the month. This ensures the data is relatively recent, which provides buyers with a more accurate picture of the marketplace.

Comment: One commenter offered the following recommendations to reduce price variability without implementing this rule: (1) Reject offers for products that fall outside of an acceptable pricing range compared to the contract-prices for identical products; (2) assure offers are authorized resellers; (3) encourage vendors to update their GSA Advantage!® catalogs and remove products that are no longer available; (4) increase customer training to reinforce the requirements of FAR subpart 8.4; (5) collect data internally to test transactional data concepts; and (6) eliminate the PRC.[172]

Response: GSA's responses to each item are as follows:

(1) GSA concurs. It is pursuing this objective with its Formatted Product Tool (FPT), which identifies pricing outside a range determined to be acceptable for identical items; vendors whose prices exceed the acceptable range are then notified of their comparative pricing.

(2) As noted by the commenter in their full comment, GSA requires offerors to submit letters of supply/commitment. GSA works to remedy situations when it is notified that a vendor is not an authorized reseller.

(3) GSA currently encourages vendors to maintain accurate GSA Advantage!® catalogs. GSA is also working on implementing updates to GSA Advantage!® that will make it easier for vendors to maintain current catalogs.

(4) GSA is updating relevant courseware on the Federal Acquisition Institute (FAI) and Defense Acquisition University (DAU) portals to educate both customers and GSA contracting officers on how to use the data. Similarly, the courseware on how to use the FSS program and other non-FSS GWACs and multi-agency IDIQs will be updated to educate customers on the new requirements and how they can use the data collected to buy smarter. The external courseware will also highlight the additional value transactional data offers to GSA's FSS and non-FSS contracting programs and emphasize it must be viewed in the context of each procurement, taking into account desired terms and conditions, performance levels, past customer satisfaction, and other relevant information.

(5) GSA considered relying on data from transactions completed through GSA Advantage!®, but it only accounts for about 1 percent of Schedule sales. Thus, the breadth of data is not adequate to meet the Government's objectives.

(6) As noted previously, GSA is removing the PRC tracking customer provision and CSP disclosures for vendors subject to the Transactional Data Reporting requirements, in part to reduce costs and simplify procedures for industry partners.

Comment: One commenter stated GSA should provide guidelines for using transactional data, as the proposed use contradicts the proposal analysis techniques found in FAR 15.404–1.[173]

Response: GSA is developing training for Government buyers and implementing new procedures for its FSS contracting officers. Training and guidance deployed in connection with this rule emphasizes the importance of considering the best overall value (not just unit price) for each procurement, taking into account desired terms and conditions, performance levels, past customer satisfaction, and other relevant information. Additionally, the new GSAM guidance released in tandem with this rule instructs FSS contracting officers to follow the techniques found in FAR 15.404–1(b).[174]

Comment: One commenter expressed concern that GSA is announcing elements of the rule implementation on its blog, GSA Interact, and urged GSA to release such details through the **Federal Register**.

Response: GSA is committed to transparency and appreciates concerns regarding communication related to this rule. As such, we conducted a public meeting regarding the rule on April 17,

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[169] *Id.*

[170] See CGP Letter.

[171] *Id.*

[172] *Id.*

[173] See ABA Letter.

[174] Federal Acquisition Regulation section 15.404–1(b) (48 CFR 15.404–1(b)).

2015 and included additional details in this **Federal Register** notice. However, the Interact platform, as well as other Internet forums, help GSA remain transparent by providing quick, efficient methods to disseminate to, and receive information from, its stakeholders. GSA will continue to make rulemaking-related announcements through the **Federal Register**. Additionally, announcements regarding reportable data elements will be posted in the **Federal Register**. Yet, GSA intends to continue using other mediums, as appropriate, to help it maintain a dialog with its stakeholders and promote transparency.

Comment: It is unclear if the proposed data element, "Non-Federal Entity, if applicable" [175] applies to authorized state and local governments, authorized prime contractors purchasing under the FAR Part 51 authority, or another entity.[176]

Response: "Non-Federal Entity, if applicable," in both Transactional Data Reporting clauses (GSAR 552.216–75 and 552.238–74 Alternate I), applies to any non-federal user authorized to purchase from the respective contract. For the FSS clause, this can include authorized state and local users under the Cooperative Purchasing program or contractors purchasing through the FAR Part 51 authority.[177]

Comment: One commenter expressed concern that GSA's ability to unilaterally add data elements to the reporting clauses will add uncertainty for contractors.[178]

Response: The new GSAM guidance released in tandem with this rule requires FSS contracting officers and GSA program offices seeking to add new standard data elements to the reporting clauses to coordinate with the applicable category manager and obtain approval from the respective head of contracting activity (HCA) and GSA's Senior Procurement Executive. The clauses themselves also note GSA Senior Procurement Executive approval is required to add new data elements. If new data elements are approved, announcements will be made in the Vendor Support Center Web site,[179] and additional forums as necessary.

Comment: GSA should limit the rule to products and services that have "substantially similar pricing structures" for a "defined pilot program." [180]

Response: GSA considered whether Transactional Data Reporting should be applied only to certain subsets of contracts. The proposed requirement was retained for GSA's non-FSS Governmentwide vehicles because most of those contracts currently have transactional data reporting requirements that exceed those created through this rule. However, the new applicable Transactional Data Reporting clause (GSAR clause 552.216–75) will provide a consistent reporting mechanism for future non-FSS vehicles, or for current vehicles that adopt the new clause. For FSS contracts, an analysis was conducted to determine whether Transactional Data Reporting should be considered for all FSS contracts, or only those that include products or services that would allow straightforward comparisons, such as commodities with standard part numbers. While transactional data is most useful for price analysis when comparing like items, it does not mean the data is not useful when perfect comparisons cannot be made. Government buyers and FSS contracting officers will still use the data for price analysis and market research, and category managers will use the data for consumption analysis to form demand management strategies, regardless of whether the data can be used for perfect comparisons. An example is the ability to compare labor rates across contract vehicles, which is beginning to bear fruit in the form of reduced contract duplication. Consequently, GSA decided not to limit the prescription of Transactional Data Reporting to certain Schedules or Special Item Numbers.

Comment: One commenter cited several concerns regarding the rule's potential application to transportation services providers for the Federal Government. Specifically, the commenter asked whether the rule will apply to GSA's freight management program; does the rule apply to contracts between federal vendors and their suppliers; and does the rule cover commercial-to-commercial transactions. The commenter also stated the rule is outside of GSA's jurisdiction; is an unwarranted expansion of the former alternation of rates doctrine; is a violation of antitrust principles, and is implementing a new fee (the Contract Access Fee) that will be an unauthorized burden on federal vendors.[181]

Response: This rule applies to certain Federal Supply Schedule (FSS) contracts, Governmentwide Acquisition Contracts (GWACs), and Governmentwide Indefinite-Delivery, Indefinite-Quantity (IDIQ) contracts awarded by GSA. This rule does not require vendors to report transactional data on orders placed outside of these contracts and does not require them to report transactional data generated for transactions between vendors and their suppliers, or commercial-to-commercial transactions.

GSA has the authority to issue regulations relating to its contracting programs. GSA's primary statutory authorities for the FSS program are 41 U.S.C. 152(3), Competitive Procedures, and 40 U.S.C. 501, Services for Executive Agencies. For GWACs, GSA is an executive agent designated by the Office of Management and Budget pursuant to 40 U.S.C. 11302(e). Furthermore, 40 U.S.C. 121(c) authorizes GSA to prescribe regulations for its other multi-agency contracts, including Governmentwide IDIQ contracts. This rule is not an unwarranted expansion of the former alternation of rates doctrine and is not a violation of antitrust principles.

Lastly, the rule is not creating a new Contract Access Fee (CAF). Currently, GSA charges ordering activities a CAF on many of its Governmentwide Acquisition Contracts (GWACs) and Governmentwide Indefinite-Delivery, Indefinite-Quantity (IDIQ) contracts, such as Alliant and OASIS. The CAF serves a similar purpose for those contracts as the Industrial Funding Fee (IFF) does for the FSS program. These fees are generally remitted by vendors on behalf of the ordering activity but are not actually paid by the vendor. Future contracts including GSAR clause 552.216–75 may apply a CAF, but the CAF will not be applied primarily because of the clause's inclusion.

Comment: Finally, a former Multiple Award Schedule Advisory Panel member expressed his support for the rule, noting "GSA should be encouraged to implement these changes and move forward with the improvement of the management of its Government-wide contract vehicles. . ." [182]

Response: GSA appreciates the support and will continue to improve its contract solutions to serve its Government customers and the American taxpayer.

VI. Executive Orders 12866 and 13563

Executive Order (E.O.) 12866 of September 30, 1993, Regulatory

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[175] See GSAR Case 2013–G504; Docket 2014–0020; Sequence 1 (80 FR 11619 (Mar. 4, 2015)).

[176] See ABA Letter.

[177] Federal Acquisition Regulation subpart 51.1 (48 CFR 51.1).

[178] *Id.*

[179] The Vendor Support Center can be accessed at *https://vsc.gsa.gov.*

[180] See ABA Letter.

[181] See NMFTA Letter.

[182] See Perry Letter.

Planning and Review, directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 6(b) of the E.O. requires the OMB Office of Information and Regulatory Affairs (OIRA) to review regulatory actions that have been identified as significant regulatory actions by the promulgating agency or OIRA.[183] This final rule has been determined to be a significant regulatory action and was therefore subject to OIRA review. However, this rule is not a "major rule," as defined by 5 U.S.C. 804.

E.O. 13563 of January 18, 2011, Improving Regulation and Regulatory Review, supplements and reaffirms the principles of E.O. 12866 of September 30, 1993. Section 1(c) of E.O. 13563 directs agencies to "use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible." Accordingly, GSA offers the following summary of the costs and benefits associated with this final rule.

Transactional Data Reporting Costs

The total costs associated with this rule are $15 million per year for participating vendors and $2 million per year for the Federal Government.[184] These costs are attributable to GSA's Federal Supply Schedules and its other non-FSS Governmentwide IDIQ vehicles as follows:

- For FSS contracts, the new reporting requirements will be initially implemented for select Schedules and Special Item Numbers on a pilot basis. GSA estimates the costs associated with these requirements to be $12 million per year for vendors participating in the FSS pilot.[185] However, the new Transactional Data Reporting clause, GSAR Alternate I, 552.238–74 Industrial Funding Fee and Sales Reporting (Federal Supply Schedule), will be paired with changes to existing FSS pricing disclosure requirements. Specifically, FSS vendors subject to the Transactional Data Reporting rule will no longer provide CSP disclosures and will no longer be subject to the PRC tracking customer provision. GSA estimates the total burden of these existing FSS pricing disclosure requirements to be $102 million per year, with FSS pilot vendors accounting for $44 million of that burden. Therefore, replacing the existing FSS pricing disclosure requirements with transactional data reporting results in a net burden reduction of approximately $32 million per year for FSS pilot vendors.[186] Furthermore, implementing the FSS pilot without the existing CSP and PRC requirements lowers the Government's burden by about $3 million per year.[187]
- Non-FSS Governmentwide IDIQs, including GWACs, will be subject to GSAR clause 552.216–75 Transactional Data Reporting. GSA estimates the costs for vendors holding these contracts to be up to almost $3 million per year.

The estimated costs for vendors affected by this rule are limited to the time needed to implement reporting procedures and fulfill monthly reporting obligations. Implementation costs include the time to configure systems, train personnel, and institute procedures. Monthly reporting costs include the time needed for identifying reportable data, performing quality assurance checks, and transmitting the data. GSA's burden estimates account for vendors that may want to hire personnel and update information technology systems to meet the reporting requirements. Existing FSS vendors participating in the Transactional Data Reporting pilot will initially be the only ones that will absorb new reporting burdens in the course of their current contract performance. However, these vendors will not necessarily need to hire additional personnel because the rule provides a net burden reduction with the removal of the CSP and PRC disclosure requirements. Likewise, the rule does not require vendors to acquire information technology tools, although some vendors, particularly those with higher sales volume, may choose to adopt automated systems to meet the reporting requirement. Nevertheless, the new FSS reporting clause will be incorporated into existing contracts through bilateral modifications, so vendors may choose not to participate. Otherwise, the new Transactional Data Reporting clauses will apply to new contracts awarded under the pilot Schedules and Special Item Numbers and new contracts awarded under non-FSS Governmentwide IDIQ programs. As such, these new vendors will have an opportunity to evaluate the costs associated with meeting these reporting requirements prior to entering into the contract.

Transactional Data Reporting Benefits

This rule will save taxpayer dollars because it supports smarter buying practices and will improve pricing. Transactional Data Reporting supports the Government's shift towards category management and provides vendors with a more open marketplace.

GSA has found transactional data to be instrumental for improving competition, lowering pricing, and increasing transparency through its Federal Strategic Sourcing Initiative (FSSI) contracts. GSA does not expect this pilot to replicate or exceed the discounts achieved through FSSI—often up to 30 percent lower than the comparable Schedule prices—mostly because of the diversity of offerings in the greater Schedules program. Yet, GSA does anticipate lower prices in addition to other key benefits. For instance, it supports the category management principles of optimizing existing contract vehicles and reducing contract duplication. The Government can use transactional data to analyze its consumption patterns, evaluate and compare purchasing channels, and identify best-in-class solutions. Thereafter, the Government can leverage its buying power and demand management strategies to achieve taxpayer savings as it concentrates its purchases through fewer channels, which will in turn provide lower administrative costs for vendors.

Today, vendors incur heavy upfront costs when submitting an offer for an FSS contract, which is frequently the entry-point to the greater federal marketplace. They are required to supply GSA contracting officers with CSP disclosures and set up mechanisms to track their sales in order to comply with the PRC. These costs are incurred before a vendor wins any federal dollars through the FSS contract. In contrast, vendors participating in Transactional Data Reporting will only incur costs after receiving an order against their FSS contract, and the costs will only increase when they win more orders. Thus, GSA is removing barriers to entry into the federal marketplace, which GSA believes is particularly beneficial to small businesses that have fewer resources for upfront investments. With Transactional Data Reporting, GSA will use the data it collects, along with data from other sources, to determine whether an offer is fair and reasonable. As a result, fewer vendors will need to rely on outside support when preparing an offer for a GSA contract vehicle.

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[183] E.O. 12866 section 3(f) states, "'Significant regulatory action' means any regulatory action that is like to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order."

[184] See Section VIII.B for a discussion of the burden estimates in accordance with Paperwork Reduction Act requirements.

[185] *Id.*

[186] $32 million does not include costs for non-FSS contracts. It is the result of the FSS burden of the initial pilot implementation ($12.41 million), minus the share of the combined CSP and PRC burden allocated to the FSS pilot vendors ($44.03 million). The total CSP and PRC burden from Information Collection 3090–0235, if it were applied to all GSA FSS vendors, including those participating in the Transactional Data Reporting pilot, would be $101.69 million. The share of that burden allocated to the FSS pilot vendors ($44.03 million) is based on the percentage of the overall FY15 FSS sales accounted for by the FSS pilot vendors (43.2 percent).

[187] $3 million is the result of the Government's annual burden for this rule ($2.34 million) minus the share of the combined CSP and PRC burden for the Government allocated to the FSS pilot contracts ($5.58 million).

Lastly, the transactional data released to the public will provide valuable market intelligence that can be used by vendors for crafting more efficient, targeted business development strategies that incur lower administrative costs. This will be particularly beneficial for small businesses, which often do not have the resources to invest in dedicated business development staff or acquire business intelligence through third-parties.

VII. Regulatory Flexibility Act

GSA expects this final rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because it involves providing transactional data on FSS and non-FSS orders that may ultimately affect the end pricing of products offered through GSA. However, the cost to comply with the additional reporting requirement will be offset by the benefits provided by the transactional data, such as greater insight and visibility into customer buying habits and knowledge of market competition. Additional benefits to FSS vendors include the addition of the Transactional Data Reporting clause (GSAR clause 552.238–74 Alternate I) being coupled with the elimination of Commercial Sales Practices (CSP) disclosures and an alternate version of the Price Reductions clause (PRC) (GSAR clause 552.238–75) that does not include the basis of award "tracking customer" requirement.

Following receipt of the public comments in response to the proposed rule, GSA concluded the horizontal pricing ability afforded by Transactional Data Reporting would not only exceed the PRC tracking customer provision benefits, it could also alleviate the need for CSP disclosures when combined with automated commercial data sources, new data analytic tools, and improved price analysis policy. For the Schedules pilot, pairing Transactional Data Reporting with a removal of CSP disclosures and the PRC tracking customer provision will result in an average annual burden reduction of approximately $32 million for participating FSS vendors.[188] Furthermore, implementing the FSS pilot without the existing CSP and PRC requirements lowers the Government's burden by about $3 million a year.[189]

Providing the required transactional data will impose significant economic impact on all vendors, both small and other than small, doing business on GSA-managed contracts. Therefore, Final Regulatory Flexibility Analysis (FRFA) has been prepared consistent with 5 U.S.C. 603, and is summarized as follows:

1. Statement of the need for, and the objectives of, the rule.

The General Services Administration (GSA) is amending the General Services Administration Acquisition Regulation (GSAR) to require vendors to report transactional data generated from orders placed against certain contracts. The primary changes are the creation of three clauses: 552.216–75 Sales Reporting and Fee Remittance; 552.238–74 Industrial Funding Fee (IFF) and Sales Reporting, Alternate I; and 552.238–75 Price Reductions, Alternate II.

Clauses 552.238–74, Alternate I and 552.216–75 will require vendors to provide transactional data from orders placed against GSA's Governmentwide contracts. Clause 552.238–74, Alternate I applies to orders placed against Federal Supply Schedule (FSS) contract vehicles. FSS vendors that agree to the new transactional data reporting requirement will have their contracts modified to include clause 552.238–75 Price Reductions, Alternate II, which removes the basis of award tracking requirement found in the basic Price Reductions clause (PRC). These vendors will also no longer be required to provide Commercial Sales Practices (CSP) disclosures, as required by GSAR section 515.408. Removing these two disclosure requirements in favor of a new transactional data reporting clause will provide a net burden reduction for FSS vendors.

The other transactional data reporting clause, 552.216–75, applies to GSA's non-FSS contract vehicles—Governmentwide Acquisition Contracts (GWACs) and Multi-Agency Contracts (MACs). Most of these contracts already contain transactional data reporting requirements and are not subject to the FSS PRC and CSP disclosure requirements. Once implemented, the new GSAR reporting clauses will further the objective of using actual transactional data in order to negotiate better pricing for GSA's Governmentwide contracting programs and enable GSA to provide federal agencies with market intelligence and expert guidance in procuring goods and services from GSA acquisition vehicles. Additionally, collecting transactional data will allow customers to analyze spending patterns and develop new acquisition strategies to fully leverage the Government's spend. Finally, reducing FSS pricing disclosure requirements will provide vendors a net burden reduction, make FSS contracts easier to administer, and improve accessibility for new vendors.

2. Summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis.

GSA received 26 comment letters on the proposed rule, including comments from industry associations, vendors, individuals, Government stakeholders, and other interested groups. Commenters representing industry interests cited the high reporting burden imposed by the rule, while stating GSA was underestimating the potential burden. However, these commenters supported the removal of the PRC basis of award tracking customer requirement.

Other areas with significant industry concern included:

- The retention, and potential increase, of CSP disclosures.
- Releasability of the transactional data to the public.
- Using transactional data for other than one-to-one comparisons.

3. Summary of the assessment of such issues, and a statement of any changes made to the proposed/interim rule as a result of such comments.

To address concerns with its Transactional Data Reporting burden estimates, GSA reevaluated its Paperwork Reduction Act burden estimation methodology and substantially increased its burden estimates. These higher burden projections were a significant concern and they reinforced the need to couple Transactional Data Reporting with other significant forms of burden reductions.

However, Transactional Data Reporting could negate that disclosure burden because not only does it exceed the PRC tracking customer provision benefits, it could also alleviate the need for CSP disclosures when combined with automated commercial data sources, new data analytic tools, and improved price analysis policy. Consequently, GSA decided to pair the new reporting requirements with the removal of CSP disclosures and the PRC tracking customer provision, resulting in an average annual burden reduction of approximately $32 million for vendors participating in the FSS pilot.[190] GSA has also reevaluated its plans for disclosure of the reported data. Transactional data collected through the portal will be accessible only by authorized users and protected in accordance with GSA's information technology security policies. This data will be used by category managers and acquisition professionals to implement smarter buying strategies.

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[188] $32 million does not include costs for non-FSS contracts. It is the result of the FSS burden of the initial pilot implementation ($12.41 million), minus the share of the combined CSP and PRC burden allocated to the FSS pilot vendors ($44.03 million). The total CSP and PRC burden from Information Collection 3090–0235, if it were applied to all GSA FSS vendors, including those participating in the Transactional Data Reporting pilot, would be $101.69 million. The share of that burden allocated to the FSS pilot vendors ($44.03 million) is based on the percentage of the overall FY15 FSS sales accounted for by the FSS pilot vendors (43.2 percent).

[189] $3 million is the result of the Government's annual burden for this rule ($2.34 million) minus the share of the combined CSP and PRC burden for the Government allocated to the FSS pilot contracts ($5.58 million).

GSA intends to share transactional data to the maximum extent allowable to promote transparency and competition while respecting that some data could be exempt from disclosure. Accordingly, a data extract will be created for use by the general public, containing information otherwise releasable under the Freedom of Information Act; details about the public data extract will be released through a forthcoming notice in the **Federal Register**. This data will provide valuable market intelligence that can be used by vendors for crafting more efficient, targeted business development strategies that incur lower administrative costs. This will be particularly beneficial for small businesses, which often do not have the resources to invest in dedicated business development staff or acquire business intelligence through third-parties.

Finally, GSA gave consideration as to whether Transactional Data Reporting should be considered for all FSS contracts or only those that include products or services that would allow straightforward comparisons, such as commodities with standard part numbers. GSA agrees transactional data is most useful for price analysis when comparing like items, but that does not mean the data is not useful when perfect comparisons cannot be made. Government buyers and FSS contracting officers will use the data for price analysis and market research, and category managers will use the data for consumption analysis to form demand management strategies, regardless of whether the data can be used for perfect comparisons.

4. The response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the rule, and a detailed statement of any change made in the final rule as a result of the comments.

The Chief Counsel for Advocacy of the Small Business Administration provided comments in response to the proposed rule; the following is a summary of those comments and GSA's responses:

Comment: While GSA recognizes that this proposed rule will have a significant economic impact on a substantial number of small businesses, the Initial Regulatory Flexibility Analysis (IRFA) does not provide sufficient data for the public to examine the potential impact of the rule on small entities.

Response: GSA did not differentiate between small businesses and other-than-small businesses in its burden estimates because Transactional Data Reporting imposes a progressive burden-one that increases with a vendor's sales volume. Namely, monthly reporting time will increase with a vendor's applicable sales volume, as vendors with lower to no reportable sales will spend little time on monthly reporting, while those businesses with more reportable sales will face a higher reporting burden. Likewise, setup costs will be a major driver of the new reporting burden, but vendors with little to no activity on their FSS contracts will likely forgo investments in new reporting systems because the reporting burden will not be significantly more than that of the current quarterly sales reporting requirements.

However, GSA was especially mindful of small business concerns when forming this rule. For instance, tying the reporting burden to sales volume is particularly beneficial for small businesses, as they hold 80 percent of the total contracts but only account for approximately 39 percent of the sales.[191] Moreover, the decision to streamline the existing pricing disclosure requirements was partially motivated by the positive impact on small businesses. Unlike the new data reporting requirements, the current CSP and PRC disclosure requirements are constant, meaning vendors, especially those with a higher number of FSS contract offerings, must bear the burden even if they have little to no sales through their FSS contracts. Thus, small businesses are disproportionately affected because they account for the bulk of lower volume contracts. Moreover, small businesses, which generally have fewer resources to devote to contract management, will no longer be subjected to the complex CSP and PRC pricing disclosure requirements.

The public data extract will also benefit small businesses. GSA intends to share transactional data to the maximum extent allowable to promote transparency and competition while respecting that some data could be exempt from disclosure. The data will serve as valuable market intelligence for vendors to use for crafting more efficient, targeted business development strategies that incur lower administrative costs. This will be particularly beneficial for small businesses, which often do not have the resources to invest in dedicated business development staff or acquire business intelligence through third-parties. Details about the public data extract will be released in a forthcoming **Federal Register** notice.

Comment: Small businesses are concerned that the IRF A for this transactional data collection and reporting rule does not provide them with a clear understanding of GSA's legal framework for requiring this new system.

Response: GSA will be implementing the Transactional Data Reporting clauses through bilateral modifications on existing contracts, meaning vendors must agree to the changes before GSA can insert a new clause in a contract. New contracts awarded under the pilot Schedules/Special Item Numbers or future Governmentwide indefinite-delivery indefinite-quantity (IDIQ) vehicles will include the new Transactional Data Reporting clauses, but vendors will have an opportunity to view the requirements before agreeing to a contract. For the Schedules, GSA is instituting this program to meet its obligations under 41 U.S.C. 152(3)(b), which states that orders and contracts awarded under the FSS program must result in "the lowest overall cost alternative to meet the needs of the Federal Government."

Comment: Small businesses expressed some of the similar concerns as shared by the GSA Office of Inspector General during the public forum. The IG stated that the proposed rule under estimates the burden and resources.

Response: As a result of these comments, GSA reevaluated its estimation methodology and recalculated the burden based on whether vendors use automated or manual systems to identify and report transactional data. An automated system is one that relies on information technology, such as an accounting system or data management software, to identify and compile reportable data. These systems can tremendously streamline the reporting process but require upfront configuration to perform the tasks, such as coding the data elements to be retrieved. Conversely, a manual system is one that incorporates little to no automation and instead relies on personnel to manually identify and compile the reportable data. An example of a manual system would be an accountant reviewing invoices to identify the reportable data and then transferring the findings to a spreadsheet. In contrast to automation, a manual system requires relatively little setup time but the reporting effort will generally increase with the vendor's sales volume.

The likelihood of a vendor adopting an automated system increases with their applicable sales volume. Vendors with little to no reportable data are unlikely to expend the effort needed to establish an automated reporting system since it will be relatively easy to identify and report a limited amount of data. In fiscal year 2015, 32 percent of FSS vendors reported $0 sales, while another 34 percent reported average sales between $1 and $20,000 per month. If the rule were applied to the entire Schedules program, approximately two-thirds, or nearly 11,000 vendors, would have a lower reporting burden. However, as a vendor's applicable average monthly sales increase, they will be increasingly likely to establish an automated system to reduce the monthly reporting burden. Consequently, vendors with higher reportable sales will likely bear a higher setup burden to create an automated system, or absorb a high monthly reporting burden if they choose to rely on manual reporting methods.

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[190] $32 million does not include costs for non-FSS contracts. It is the result of the FSS burden of the initial pilot implementation ($12.41 million), minus the share of the combined CSP and PRC burden allocated to the FSS pilot vendors ($44.03 million). The total CSP and PRC burden from Information Collection 3090–0235, if it were applied to all GSA FSS vendors, including those participating in the Transactional Data Reporting pilot, would be $101.69 million. The share of that burden allocated to the FSS pilot vendors ($44.03 million) is based on the percentage of the overall FY15 FSS sales accounted for by the FSS pilot vendors (43.2 percent).

[191] Based on fiscal year 2015 Federal Supply Schedule contract data.

This renewed analysis led GSA to increase its burden estimates. For FSS contracts in particular—

- The projected setup time for an automated system increased from an average of 6 hours[192] to an average of 240 hours; and
- The projected monthly reporting time range grew from 0.3 minutes–4 hours to 0.25 hours–48 hours.

However, GSA's estimates are still considerably lower than the estimates provided through the public comments,[193] primarily because—

- At least two-thirds of the potential Transactional Data Reporting participants will have a relatively lower burden (*e.g.,* vendors with lower or no sales); and
- Vendors with higher reporting volume will face lower setup times with a higher monthly reporting burden, or higher setup times with a lower monthly reporting burden. In other words, vendors will not face a higher setup burden and a higher monthly reporting burden to comply with the rule.

Comment: Small businesses fear that the proposed rule will have unintended consequence of further reduction of an already reduced federal small business industrial base. Small businesses in this regard point to the negative impact of Strategic Sourcing (SS) on the number of small businesses that are now participating in the federal procurement system. Some postulate that SS has not harmed the small business community citing the actual dollars being awarded to small businesses. However, while the dollars are increasing the actual participation rate of small businesses is decreasing.

Response: GSA will be mindful of Transactional Data Reporting's small business impacts. The initiative is being phased in on a pilot basis. GSA's Senior Procurement Executive will regularly evaluate progress against metrics, including small business participating, in consultation with the Administrator for Federal Procurement Policy and other interested stakeholders to determine whether to expand, limit, or discontinue the program. No expansion of the pilot or action to make Transactional Data Reporting a permanent fixture on the Schedules will occur prior to the careful evaluation of at least one year of experience with the pilot.

Comment: GSA will sort the monthly reporting of the transactional data and share it across the federal government but small businesses are concerned that the proposed rule does not contemplate privacy issues nor other proprietary business concerns. Small businesses have concerns about how transactional data will be protected from competitors.

Response: Transactional data reported in accordance with this rule will be accessible only by authorized Government users. GSA intends to share the transactional data with the public to the maximum extent allowable while respecting that some data could be exempt from disclosure. Consequently, a data extract will be created for use by the general public, containing information otherwise releasable under the Freedom of Information Act (FOIA);[194] details about the public data extract will be released through a forthcoming notice in the **Federal Register**.

Transparency will support a dynamic marketplace by providing contractors with the business intelligence needed to identify customers, determine which products should be included on their contract pricelists, and ascertain whether their prices are competitive. This will be particularly beneficial for small businesses, which often do not have the resources to invest in dedicated business development staff or acquire business intelligence through third-parties.

However, GSA recognizes some information may be protected from public release, which led to the decision to create a public data extract, as opposed to allowing the public the same access as authorized users. The data extract will provide the public a filtered view of the data, including information that is releasable under FOIA while protecting information that is not.

Comment: Small business owners are concerned that this new vision of transactional data reporting and utilization will reduce the values added that they bring to an acquisition process. The proposal's new vision and the transactional proposal would seem to place price as opposed to best value as its single most important consideration for contract award. Best value has emerged over the years as a strong federal government benchmark for evaluating and awarding contracts and it allows for small businesses to compete on a more level playing field. While trying to improve the acquisition process, the government should not abandon this long established and proven acquisition tool. Price should not be the sole measure of awarding a contract.

Response: Transactional data will not transform the federal acquisition system into a lowest-price procurement model. The Federal Acquisition Regulation (FAR) has a stated vision "to deliver on a timely basis the best value product or service to the customer, while maintaining the public's trust and fulfilling public policy objectives."[195] The Government's preference will continue to be "best value," or defined in the FAR, "the expected outcome of an acquisition that, in the Government's estimation, provides the greatest overall benefit in response to the requirement."[196] Transactional data is viewed in the context of each procurement, taking into account desired terms and conditions, performance levels, past customer satisfaction, and other relevant information. Using and understanding the data will help inform requirements definition and reduce excess consumption.

Comment: The proposed rule would seem to require contractors to pay a Contractor Access Fee (CAF) fee and an industrial funding fee. The proposed rule is unclear as to how these fees interact with each other.

Response: The Contract Access Fee (CAF) and Industrial Funding Fee (IFF) will not be charged in tandem. The IFF is applied to GSA's Federal Supply Schedule contracts while the CAF is only applied to GSA's other Governmentwide vehicles, such as Governmentwide Acquisition Contracts (GWACs), indefinite-delivery indefinite-quantity (IDIQ), and other multi-agency contracts.

Comment: Because of the economic impact of this proposed regulation on a substantial number of small entities, GSA should extend the comment period for an additional sixty days and conduct field hearings in other parts of the United States.

Response: GSA extended the proposed rule comment period from May 4, 2015 to May 15, 2015. Additionally, the public meeting it held on April 17, 2015 in Washington, DC was accessible through an Internet simulcast to interested parties outside of the Washington, DC area. In total, the meeting was attended by 120 in-person participants and 153 remote attendees.

Comment: GSA should conduct a more detailed impact assessment of this proposed rule on small businesses. During the April 17, 2015 public forum, Advocacy asked GSA if an analysis had been performed on the impact of this rule on small businesses and GSA's response was to cite the number of small businesses that are on schedule and the dollar amount being awarded to these businesses. However this statement does not delve into the more structural issue of small business commodity pricing. Since most small businesses that are on a GSA schedule are value added resellers and since many of the original equipment makers are also on GSA schedules it is unclear because of the lack of data how GSA will balance the potential conflict of these two types of business entities.

Response: Pricing will not be GSA's sole consideration when awarding items on its Governmentwide contract vehicles, and the Government will continue to have a preference for best value solutions. However, when price is evaluated, it will be done so within a range, as GSA recognizes other factors should be taken into consideration, such as socio-economic concerns. For example, GSA is beginning to employ automated analysis techniques for its contract-level prices to reduce variability. GSA recently launched its Formatted Product Tool (FPT) that identifies pricing outside a range determined to be acceptable for identical items; vendors whose prices exceed the acceptable range are then notified of their comparative pricing. Currently, this initiative applies only to products, while services will be addressed at a later date. However, whether it be the FPT or other tools, it is important to note GSA intends to view pricing in a range, so renegotiations will not be triggered merely because a vendor does not meet the lowest-reported price.

5. Description and an estimate of the number of small entities to which the rule will apply.

The reporting clauses created by this rule will initially apply to a subset of the GSA's

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[192] The proposed rule setup time estimates did not differentiate between manual and automated reporting systems.

[193] One commenter provided its own estimates on the reporting burden.

[194] 5 U.S.C. 552.

[195] Federal Acquisition Regulation section 1.102 (48 CFR 1.102).

[196] Federal Acquisition Regulation section 2.101 (48 CFR 2.101).

Federal Supply Schedule program on a pilot basis and will be available for use for all of GSA's non-FSS Governmentwide IDIQ contracts. This population consists of 6,017 contracts, of which 4,852 (81 percent) are held by small business concerns. The vast majority of these small business contracts (4,358) are under GSA's FSS program.

This rule may eventually apply to all contractors who hold GSA Federal Supply Schedule contracts and other GSA Governmentwide contract vehicles. This population consists of 20,323 contracts, 16,308 (80 percent) of which are held by small businesses. The vast majority of these small businesses contracts (15,837) are under GSA's FSS program.

6. A description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the requirement and the type of professional skills necessary for preparation of the report or record.

Vendors subject to the rule will be required to report transactional data and remit fees paid by ordering activities to GSA. The data reporting responsibilities are new for FSS vendors, but most of GSA's Governmentwide non-FSS contracts already contain transactional data reporting requirements.

The reporting aspect of the rule requires vendors to identify, compile, and report transactional data—historical information encompassing the products and services delivered during the performance of a task or delivery order placed against this contract. Furnishing electronic reports is an existing requirement for all affected vendors but FSS vendors will be required to furnish more detailed information than currently required under their FSS contracts. The clauses require vendors to report data once a month—within 30 days after the last day of the end of the month.

Vendors will be responsible for remitting applicable fees paid by ordering activities to GSA. FSS vendors must remit fees four times a year (30 days after the end of the last day of each quarter) and non-FSS vendors may have to remit fees up to, but no more than, once a month. These fee remittance requirements are generally the same as what is currently required under these contracts.

The reporting clauses created by this rule will initially apply to a subset of the GSA's Federal Supply Schedule program on a pilot basis and will be available for use for all of GSA's non-FSS Governmentwide IDIQ contracts; this population consists of 6,017 contracts, of which 4,852 (81 percent) are held by small business concerns. This rule may eventually apply to all contractors who hold GSA Federal Supply Schedule contracts and other GSA Governmentwide contract vehicles; this population consists of 20,323 contracts, 16,308 (80 percent) of which are held by small businesses. These small business contract holders include SBA certified 8(a) firms; SBA certified small disadvantaged businesses; HUBZone firms; service disabled veteran-owned small businesses; veteran-owned small businesses; economically disadvantaged women-owned small businesses; and women-owned small businesses.

The professional skills needed to comply with these requirements are generally the same as those needed to comply with existing FSS and non-FSS reporting requirements and invoicing functions. Generally, reporting personnel must have an understanding of the reporting system and the transactional data they are reporting.

7. An account of the steps taken to minimize the significant economic impact of the rule on small entities consistent with the stated objectives of applicable statutes, including:

- *A statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule; and*
- *Why each one of the other considered significant alternatives, that affect the impact on small entities, was rejected.*

GSA determined it is necessary to obtain and analyze transactional data for purchases made through its contract vehicles in order to support the Government's category management vision and improve acquisition outcomes in general. For the Schedules, GSA is instituting this program to meet its obligations under 41 U.S.C. 152(3)(b), which states that orders and contracts awarded under the FSS program must result in "the lowest overall cost alternative to meet the needs of the Federal Government."

Following the April 17, 2015 public meeting and subsequent receipt of the public comments, GSA was compelled to further evaluate the spectrum of alternatives for Transactional Data Reporting, ranging from withdrawing the rule in favor of different approaches for obtaining the data to applying the new reporting clauses without corresponding changes to existing disclosure requirements. Ultimately, the decision to proceed hinged on considerations including, but not limited to, alternatives for collecting transactional data; the burden associated with reporting transactional data; opportunities to reduce burden through changes to existing disclosure requirements, and the associated impacts of those changes; effects on small businesses; and the benefits of collecting transactional data for non-standard products and services.

GSA's Initial Regulatory Flexibility Analysis included an evaluation of alternatives for obtaining transactional data—internal applications; GSA ordering platforms such as eBuy and GSA Advantage!®; the SmartPay credit card purchase program; and upgrades to the Federal Procurement Data System. GSA previously concluded these options would not provide the breadth of data needed to support the Government's objectives or would be unable to do so in the foreseeable future. Since the publication of the proposed rule, GSA reevaluated those alternatives and reached similar conclusions. Additionally, the Government's electronic invoicing initiative [197] was assessed as a potential alternative. However, following meetings regarding electronic invoicing implementation with representatives from the Department of Defense, Department of Energy, Department of Transportation, Department of Treasury, and Department of Veterans Affairs, it was determined these electronic invoicing platforms will not provide a Government-wide transactional data reporting solution in the near term. Consequently, GSA continued to evaluate solutions that relied on vendor-provided transactional data.

The most common concern, in terms of the number of respondents, regarded the associated burden of reporting transactional data. In general, commenters felt the burden was underestimated and/or the requirement was too burdensome. To address the concerns with its Transactional Data Reporting burden estimates, GSA reevaluated its methodology and substantially increased its burden estimates. These higher burden projections were a significant concern and they reinforced the need to couple Transactional Data Reporting with other significant forms of burden reductions.

A notable concern expressed by industry stakeholders was the retention, and potential increase, of CSP disclosures. GSA noted in the proposed rule it ". . . would maintain the right throughout the life of the FSS contract to ask a vendor for updates to the disclosures made on its commercial sales format (which is used to negotiate pricing on FSS vehicles) if and as necessary to ensure that prices remain fair and reasonable in light of changing market conditions." [198] In response, industry stakeholders indicated retaining CSP disclosures would undercut any burden reduction achieved by eliminating the PRC tracking customer requirement. Specifically, respondents were concerned CSP disclosures will still force them to monitor their commercial prices, which ultimately causes the associated burden for both disclosure requirements.

In 2015, GSA also began preparing its request to renew the PRC information collection request (ICR) in accordance with the Paperwork Reduction Act of 1995.[199] While GSA would have proceeded with a renewal request regardless of this case, the timing did allow for the consideration of the Transactional Data Reporting comments. GSA agreed with the general comment that burdens of the PRC and CSP are related; as a result, it included CSP disclosure burden estimates in the ICR and renamed it "Federal Supply Schedule Pricing Disclosures" to more accurately reflect the scope of the information collected.

Following two **Federal Register** notices requesting comments on the FSS Pricing Disclosures ICR,[200] GSA increased its annual burden estimates for GSA FSS vendors, including those who would participate in the Transactional Data Reporting pilot, from $59 million[201] to $102 million.[202] Yet, Transactional Data Reporting alleviates the need for these FSS pricing disclosures when combined with automated commercial data sources, new data analytic tools, and improved price analysis policy. As a result, GSA decided to pair Transactional Data Reporting with the removal of CSP disclosures and the PRC tracking customer provision, resulting in an average annual burden reduction of approximately $32 million for participating FSS vendors.[203] Furthermore, implementing the FSS pilot without the existing CSP and PRC requirements lowers the Government's burden by about $3 million a year.[204]

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[197] See Office of Management and Budget memorandum M–15–19, "Improving Government Efficiency and Saving Taxpayer Dollars Through Electronic Invoicing", July 17, 2015, available at *https://www.whitehouse.gov/sites/default/files/omb/memoranda/2015/m-15-19.pdf.*

[198] See GSAR Case 2013–G504; Docket 2014–0020; Sequence 1 (80 FR 25994 (May 6, 2015)).

[199] Public Law 104–13, 109 Stat. 163.

[200] See 80 FR 72060 (Nov. 18, 2015) and 81 FR 21346 (Apr. 11, 2016).

Streamlining the existing pricing disclosure requirements is particularly beneficial for small businesses. The current CSP and PRC disclosure requirements are constant, meaning vendors, especially those with a higher number of FSS contract offerings, must bear the burden even if they have little to no sales through their FSS contracts. Thus, small businesses are disproportionately impacted because they account for the bulk of lower volume contracts. Moreover, small businesses, which generally have fewer resources to devote to contract management, will no longer be subjected to the complex CSP and PRC pricing disclosure requirements.

The Regulatory Secretariat has submitted a copy of the Final Regulatory Flexibility Analysis (FRFA) to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the FRFA may be obtained from the Regulatory Secretariat.

VIII. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. Chapter 35) applies to this final rule because it contains information collection requirements. Accordingly, the Regulatory Secretariat submitted a request for approval of a new information collection requirement concerning this rule to the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

GSA has increased its burden estimates for the final rule. For the proposed rule, GSA chose to estimate the burden for the entire population of contracts that may ultimately be affected by this rule. However, as this rule will only initially apply to select Schedules and SINs under the FSS program on a pilot basis, GSA is now estimating the burden impact for vendors participating in the FSS pilot and those holding other GSA Governmentwide contracts that may include the Transactional Data Reporting clause (552.216–75). Although the burden estimates have increased, the final rule will still provide a net burden reduction based on the difference between the CSP and PRC disclosure requirements and the new reporting requirements (*i.e.*, clauses 552.238–74 Alternate I and 552.216–75). An analysis of these burden estimates, as well as the underlying assumptions, is presented below.

A. New Reporting Requirements

The new reporting clauses require vendors to report transactional data elements such as item descriptions and prices paid to a GSA Web site. This data must be reported monthly within 30 calendar days after the of each calendar month, meaning vendors will furnish 12 reports over the course of a year for each contract containing one of these clauses.

Categorization of Vendors by Monthly Sales Revenue: Transactional Data Reporting imposes a progressive burden—one that increases with a vendor's sales volume. Monthly reporting times will increase with a vendor's applicable sales volume, as vendors with lower to no reportable sales will spend little time on monthly reporting, while those with more reportable sales with face a higher reporting burden.

The reporting clauses created by this rule will initially apply to a subset of the FSS program on a pilot basis and will be available for use for all of GSA's non-FSS Governmentwide IDIQ contracts. The pilot population may include up to 4,978 FSS vendors and 537 non-FSS vendors, for a total of 5,515 vendors. However, this number may be lower depending on the number of FSS vendors that accept the bilateral modification to include GSAR clause 552.238–74 Alternate I, or whether existing non-FSS Governmentwide contracting programs opt not to use GSAR clause 552.216–75.

GSA separated vendors into categories based on average monthly sales volume[205] in order to account for the differences in reporting burden. These categories are:

- Category 1: No sales activity (average monthly sales of $0).
- Category 2: Average monthly sales between $0 and $20,000.
- Category 3: Average monthly sales between $20,000 and $200,000.
- Category 4: Average monthly sales between $200,000 and $1 million.
- Category 5: Average monthly sales over $1 million.

The distribution by sales category of vendors initially impacted by this rule (*i.e.*, the pilot) is as follows:

FSS AND NON-FSS VENDORS BY SALES CATEGORY

	FSS vendors (count)	FSS vendors (percentage)	Non-FSS vendors (count)	Non-FSS vendors (percentage)	Total vendor count by category
Category 1	1,343	26.98	31	5.77	1,374
Category 2	1,800	36.19	42	7.82	1,842
Category 3	1,219	24.49	196	36.50	1,415
Category 4	426	8.56	173	32.22	599
Category 5	190	3.82	95	17.69	285

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[201] The 2012 information collection did not provide a cost burden estimate, but if the same hourly rate ($68) was applied to the 2012 time burden, the 2012 cost burden would have been $59,086,560.

[202] The annual public reporting burden for the CSP and PRC, excluding FSS vendors participating in the Transactional Data Reporting pilot, is $57.66 million. If FSS pilot vendors were still subject to the CSP and PRC reporting requirements, the total annual public reporting burden would be $101.69 million. The FSS pilot vendors' share of the total CSP and PRC reporting burden is based upon their share of the GSA FSS fiscal year 2015 sales volume, 43.2 percent. The annual $44.03 million reporting burden reduction attributed to this rule is 43.2 percent of the $101.69 million annual reporting burden if it were applied to the entire GSA FSS program. More information about Information Collection 3090–0235 can be found at *http://www.reginfo.gov/public* by searching "ICR" for "3090–0235".

[203] $32 million does not include costs for non-FSS contracts. It is the result of the FSS burden of the initial pilot implementation ($12.41 million), minus the share of the combined CSP and PRC burden allocated to the FSS pilot vendors ($44.03 million). The total CSP and PRC burden from Information Collection 3090–0235, if it were applied to all GSA FSS vendors, including those participating in the Transactional Data Reporting pilot, would be $101.69 million. The share of that burden allocated to the FSS pilot vendors ($44.03 million) is based on the percentage of the overall FY15 FSS sales accounted for by the FSS pilot vendors (43.2 percent).

[204] $3 million is the result of the Government's annual burden for this rule ($2.34 million) minus the share of the combined CSP and PRC burden for the Government allocated to the FSS pilot contracts ($5.58 million).

[205] Average monthly sales volume was computed by taking a vendor's total annual sales volume and dividing it by 12. All FSS and non-FSS sales figures are based on FY2015 sales data.

FSS and Non-FSS Vendors by Sales Category—Continued

	FSS vendors (count)	FSS vendors (percentage)	Non-FSS vendors (count)	Non-FSS vendors (percentage)	Total vendor count by category
Total	4,978	100.00	537	100.00	5,515

Automated vs. Manual Reporting Systems: Vendors subject to these clauses must create systems or processes to produce and report accurate data. Generally, vendors will use automated or manual systems to identify the transactional data to be reported each month. An automated system is one that relies on information technology, such as an accounting system or data management software, to identify and compile reportable data. These systems can tremendously streamline the reporting process but require upfront configuration to perform the tasks, such as coding the data elements to be retrieved. Conversely, a manual system is one that incorporates little to no automation and instead relies on personnel to manually identify and compile the reportable data. An example of a manual system would be an accountant reviewing invoices to identify the reportable data and then transferring the findings to a spreadsheet. In contrast to automation, a manual system requires relatively little setup time but the reporting effort will generally increase with the vendor's sales volume.

The likelihood of a vendor adopting an automated system increases with their applicable sales volume. Vendors with little to no reportable data are unlikely to expend the effort needed to establish an automated reporting system since it will be relatively easy to identify and report a limited amount of data. In fiscal year 2015, 32 percent of FSS vendors reported $0 sales, while another 34 percent reported average sales between $1 and $20,000 per month. If the rule were applied to the entire Schedules program, approximately two-thirds, or nearly 11,000 vendors, would have a lower reporting burden. However, as a vendor's applicable average monthly sales increase, they will be increasingly likely to establish an automated system to reduce the monthly reporting burden. Consequently, vendors with higher reportable sales will likely bear a higher setup burden to create an automated system, or absorb a high monthly reporting burden if they choose to rely on manual reporting methods.

The following chart depicts the likelihood of the pilot population of vendors initially impacted by this rule adopting manual and automated reporting systems:

Vendors by Reporting System Type

[Manual vs. automated]

	Manual system (percentage)	Automated system (percentage)	Manual system—vendor count	Automated system—vendor count
Category 1	100	0	1,374	0
Category 2	100	0	1,842	0
Category 3	90	10	1,274	142
Category 4	50	50	299	300
Category 5	10	90	29	257
Total Count of Vendors by System Type			4,818	698
Percentage of Vendors by System Type			87.35	12.65

Initial Setup: Vendors complying with this rule will absorb a one-time setup burden to establish reporting systems. The estimated setup time varies between automated and manual reporting systems. Vendors implementing a manual system must acclimate themselves with the new reporting requirements and train their staff accordingly, while those with automated systems must perform these tasks in addition to configuring information technology resources. GSA is attributing the setup burden by vendor, not by contracts, because a vendor holding multiple contracts subject to this rule will likely use a single reporting system. GSA estimates the average one-time setup burden is 8 hours for vendors with a manual system and 240 hours for those with an automated system.

Monthly Reporting: After initial setup, vendors subject to these reporting clauses are required to report transactional data within 30 calendar days after the end of each calendar month. The average reporting times vary by system type (manual or automated) and by sales category. GSA estimates vendors using a manual system will have average monthly reporting times ranging from 15 minutes (0.25 hours) per month for vendors with $0 sales, to an average of 48 hours per month for vendors with monthly sales over $1 million. On the other hand, GSA projects vendors with automated systems will have reporting times of 2 hours per month, irrespective of monthly sales volume, as a result of efficiencies achieved through automated processes.

The following table shows GSA's projected monthly reporting times per sales category and system type:

Monthly Reporting Hours by System Type and Category

	Manual systems	Automated systems
Category 1	0.25	2.00
Category 2	2.00	2.00
Category 3	4.00	2.00
Category 4	16.00	2.00
Category 5	48.00	2.00

B. Annualized Public Burden Estimates

The time and cost estimates for vendors initially impacted by the rule (*i.e.*, the pilot) include one-time setup and monthly reporting burdens to comply with both reporting clauses.

Cost estimates were calculated by multiplying the estimated burden hours by an hourly rate of $68 ($50/hour with a 36 percent overhead rate[206]). However, other aspects of the calculation methodology vary between FSS and non-FSS vendors:

- FSS estimates are made on a 20-year contract life cycle because the maximum length of an FSS contract is 20 years. The estimates include a one-time setup burden for all 4,978 FSS pilot vendors in Year 1. For each year thereafter, the estimates include the one-time setup burden for new FSS vendors under the pilot Schedules and SINs[207] and the monthly reporting burden for all impacted FSS vendors. The total Year 1 hours and costs were added to the aggregate hours and costs from Years 2 through 20 to arrive at the total life cycle figures, and then those figures were divided by 20 to arrive at the average annual figures:

FSS Burden.

Year 1 Time Burden: 321,064 hours.

Year 1 Cost: $21,832,365.60.

Years 2 through 20 Average Annual Time Burden: 175,239 hours.

Years 2 through 20 Average Annual Cost Burden: $11,916,272.42.

Total Average Annual Time Burden: 182,531 hours.

Total Average Annual Cost Burden: $12,412,077.08.

- Non-FSS estimates are made on a 10-year contract life cycle because the maximum length of a non-FSS contract is 10 years. The estimates include a one-time setup burden for all 537 non-FSS vendors in Year 1. For each year thereafter, the estimates only include the monthly reporting burden because contracts are typically not added to a non-FSS program following the initial awards. The total Year 1 hours and costs were added to the aggregate hours and costs from Years 2 through 10 to arrive at the total life cycle figures, and then those figures were divided by 10 to arrive at the average annual figures.

Non-FSS Burden.

Year 1 Time Burden: 84,994 hours.

Year 1 Cost Burden: $5,779,578.40.

Years 2 through 10 Average Annual Time Burden: 36,247 hours.

Years 2 through 10 Average Annual Cost Burden: $2,464,768.80.

Total Average Annual Time Burden: 41,121 hours.

Total Average Annual Cost Burden: $2,796,249.76.

Based on this methodology, the average annual time burden for vendors initially complying with this rule is 205,900 hours:

Average Annual Time Burden.

FSS Pilot Vendors (Clause 552.238–74 Alternate I): 182,531 hours.

Non-FSS Vendors (Clause 552.216–75): 41,121 hours.

Total Average Annual Time Burden: 223,652 hours.

The average annual cost burden for vendors initially complying with this rule is $15,208,326.84:

Average Annual Cost Burden.

FSS Pilot Vendors (Clause 552.238–74 Alternate I): $12,412,077.08.

Non-FSS Vendors (Clause 552.216–75): $2,796,249.76.

Total Average Annual Time Burden: $15,208,326.84.

C. Annualized Federal Government Burden Estimates

The Government also incurs costs through this rule when collecting data and performing quality assurance functions. Cost estimates use an hourly rate of $41.48, which is derived from a GS–12, Step 5 salary in the Washington, DC locality area.[208] The burden includes costs specific to FSS contracts, non-FSS contracts, and information technology systems:

- *FSS Contracts:* Industrial Operations Analysts (IOAs) conduct compliance reviews that include analyzing the completeness and accuracy of reported data. IOAs are also responsible for reviewing reported data and data corrections, as necessary. IOAs reported spending 62,769 hours on compliance reviews in fiscal year 2014. GSA personnel spent approximately 1 hour reviewing 2,851 sales adjustments over that same time period, a task that has since been transferred to IOAs. Therefore, the total time estimate for FSS contracts is 65,620 hours per year, for an estimated annual cost of $2,721,927.97.
- *Non-FSS Contracts:* GSA personnel estimated it currently takes them an average of 2.5 hours per contract per month to process transactional data. Multiplied by the number of applicable non-FSS contracts in fiscal year 2015 (537), this equates to 16,110 hours, or an estimated annual cost of $668,242.80.
- *Information Technology Systems:* The system needed to collect and process transactional data will cost GSA an average of $491,500.00, spread across a 20-year contract life cycle.

Combining the costs for FSS contracts, non-FSS contracts, and information technology systems, the total annualized cost to the Government for the reporting clauses would be $3,881,670.77 if the rule were implemented across the FSS program.[209] However, since the rule is being implemented for the FSS program on a pilot basis for select Schedules and SINs, the initial implementation costs only include a share of the full FSS implementation burden. As the pilot contracts represented 43.2 percent of the total fiscal year 2015 FSS sales, GSA is allocating the same share for the FSS burden relating to IOAs, which amounts to $1,175,872.88. As a result, the initial Government burden is $2,335,615.68.

D. Differences From the Previous Burden Estimates

Nineteen commenters provided comments related to the compliance burden.[210] Several questioned GSA's burden projections, stating the compliance estimates were understated and the projected burden reduction was overstated. Multiple commenters stated the Government is shifting the burden of gathering transactional data onto vendors, with some suggesting the burden will lead to higher prices or that vendors should be reimbursed for costs incurred.

The proposed rule contained burden estimates in accordance with the Paperwork Reduction Act, including a one-time average initial setup burden of 6 hours and an average monthly reporting burden of approximately .52 of an hour, or 31 minutes. The ongoing reporting burden for FSS vendors, following a first-year burden for implementation, was estimated to $7.6 million a year. However, the proposed rule coupled the new reporting requirements with the removal of the PRC tracking customer provision, which was projected to provide an estimated burden reduction of approximately $51 million a year if the rule were applied to the entire GSA Schedules program,[211] based upon PRC burden estimates from the 2012 approval of the information collection tracked under OMB Control Number 3090–0235.

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[206] The 36 percent overhead rate was used in reference to Office of Management and Budget (OMB) Circular No. A–76. Circular A–76 requires agencies to use standard cost factors to estimate certain costs of Government performance. These cost factors ensure that specific government costs are calculated in a standard and consistent manner to reasonably reflect the cost of performing commercial activities with government personnel. The standard cost factor for fringe benefits is 36.25 percent; GSA opted to round to the nearest whole number for the basis of its burden estimates.

[207] 1,434 vendors were awarded a total of 1,493 FSS contracts in FY2015. The 1,434 figure was used to project the number of new vendors each year from Years 2 through 20.

[208] Office of Personnel Management Salary Table 2015–DCB Washington-Baltimore-Northern Virginia, DC-MD-VA-WV-PA, effective January 2015.

[209] Excluding costs for FSS contracts administered by the Department of Veterans Affairs.

[210] See *e.g.*, ABA Letter, Abt Associates Letter, Allen Letter, ARA Letter, CGP Letter, CODSIA Letter, EA Letter, Experian Letter, GSA OIG Letter, immixGroup Letter, IOPFDA Letter, Insite.rr.com Letter, Johnson & Johnson Letter, NDIA Letter, POGO Letter, RTI Letter, SBA Letter, Shepra Letter, SIA Letter.

Coincidentally, GSA began preparing its request to renew Information Collection 3090–0235 in the summer of 2015, as it was due to be renewed three years after its 2012 approval. While GSA would have proceeded with a renewal request regardless, the timing did allow for consideration of the Transactional Data Reporting comments. In particular, GSA agreed with the general industry comment that the burdens of the PRC and CSP are related, and GSA therefore decided to include CSP disclosure burden estimates in its information collection request. Following two **Federal Register** notices requesting comments on the FSS Pricing Disclosures ICR,[212] GSA increased its annual burden estimates for GSA FSS vendors, including those who would participate in the Transactional Data Reporting pilot, from $59 million [213] to $102 million.[214]

To address the concerns with the Transactional Data Reporting proposed rule burden estimates, GSA reevaluated its methodology and substantially increased its burden estimates. For the proposed rule, GSA's public burden estimates included an average initial setup time of 6 hours and average ongoing monthly reporting times ranging from 2 minutes to 4 hours, depending on a vendor's sales volume.[215] In contrast, the final rule burden estimates include initial average setup times of 8 hours for vendors using manual systems and 240 hours for vendors using automated systems, and average ongoing monthly reporting times ranging from 15 minutes to 48 hours, depending on a vendor's sales volume and reporting system type.

These higher burden projections, coupled with the increased Transactional Data Reporting burden estimates calculated in response to the public comments, were a significant concern and reinforced the need to pair Transactional Data Reporting with other significant forms of burden reductions. Consequently, the FSS Transactional Data Reporting clause (552.238–74 Alternate I) is now coupled with the removal of the CSP and PRC burdens shown in Information Collection 3090–0235, resulting in an overall annual public burden reduction of approximately $32 million for the initial implementation of the rule.[216] Furthermore, implementing the FSS pilot without the existing CSP and PRC requirements lowers the Government's burden by about $3 million a year.[217]

E. Information Collection Supporting Statement

Requesters may obtain a copy of the supporting statement from the General Services Administration, Regulatory Secretariat Division (MVCB), ATTN: Ms. Flowers, 1800 F Street NW., 2nd Floor, Washington, DC 20407. Please cite OMB Control Number 3090–0306, Transactional Data Reporting, in all correspondence.

Exhibit A: List of Comment Letters Received

Note: The following Exhibit A will not appear in the Code of Federal Regulations.

ABA: Letter from Stuart B. Nibley, Chair, American Bar Association, Section of Public Contract Law, May 11, 2015.

Abt Associates: Letter from Marcia King, Associate Director, Contracts, Abt Associates, May 1, 2015.

Allen: Letter from Larry Allen, President, Allen Federal Business Partners, May 4, 2015.

ARA: Letter from John McClelland, Vice President, Government Affairs & Chief Economist, American Rental Association, May 4, 2015.

Atkins: Letter from Carol Hardaker, Atkins North America, Inc., March 11, 2015.

CODSIA: Letter from Bettie McCarthy, Administrative Officer, Council of Defense and Space Industry Associations, on behalf of: R. Bruce Josten, Executive Vice President, Government Affairs, Chamber of Commerce of the U.S.; A.R. "Trey" Hodgkins, III, Senior Vice President for the Public Sector, Information Technology Alliance for the Public Sector; Will Goodman, Vice President for Policy, National Defense Industrial Association; Alan Chvotkin, Executive Vice President & Counsel, Professional Services Counsel; May 4, 2015.

CGP: Letter from Roger Waldron, President, The Coalition for Government Procurement, May 4, 2015.

deMers: Letter from Brad deMers, March 4, 2015.

EA: Letter from Frank J. Aquino, Vice President and General Counsel, EA Engineering, Science, and Technology, Inc., PBC, May 4, 2015.

Experian: Letter from Heather Richey, Experian, May 11, 2015.

Falcone: Letter from Ronald Falcone, May 4, 2015.

GSA OIG: Letter from Theodore R. Stehney, Assistant Inspector General for Auditing, GSA Office of Inspector General, Office of Audits, May 4, 2015.

immixGroup: Letter from Jeffrey Ellinport, Senior Director & Deputy General Counsel, immixGroup, May 1, 2015.

Insite.rr.com: Letter from Randall Sweeney, *Insite.rr.com,* April 22, 2015.

IOPFDA: Letter from Paul Miller, Independent Office Products and Furniture Dealers Association, March 30, 2015.

Johnson & Johnson: Letter from Colleen Menges, Director, Government Contracts, Johnson & Johnson Health Care Systems Inc., May 4, 2015.

Lynch: Letter from Rod Lynch, March 4, 2015.

Macdonald: Letter from J. Ruairi Macdonald, L.L.M. Government Procurement Law Candidate, George Washington University Law School, May 4, 2015.

NDIA: Letter from Will Goodman, Vice President for Policy, National Defense Industrial Association, April 28, 2015.

NMFTA: Letter from Paul D. Cullen, Jr. and John R. Bagileo, National Motor Freight Traffic Association, Inc., May 11, 2015.

Perry: Letter from Glenn Perry, Multiple Award Schedule Advisory Panel Member and former senior procurement official, April 17, 2015.

POGO: Letter from Scott H. Amey, General Counsel, Project on Government Oversight, May 4, 2015.

RTI: Letter from Don Enichen, Research Triangle Institute, May 11, 2015.

SBA: Letter from Claudia R. Rogers, Acting Chief Counsel for Advocacy, and Major L. Clark III, Assistant Chief Counsel for Advocacy, U.S. Small Business Administration, Office of Advocacy, May 4, 2015.

Shepra: Letter from Stephen Roadfeldt, Shepra, Inc., April 9, 2015.

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[211] The $51 million burden reduction was the ongoing FSS reporting burden ($7.6 million) minus the PRC burden of $58.5 million from the 2012 PRC information collection (OMB Control Number 3090–0235). The $7.6 million FSS reporting burden did not include the burden for one-time implementation. The $51 million burden reduction applied to the entire GSA Schedules program and was not adjusted to only account for vendors participating in the FSS pilot.

[212] See 80 FR 72060 (Nov. 18, 2015) and 81 FR 21346 (Apr. 11, 2016).

[213] The 2012 information collection did not provide a cost burden estimate, but if the same hourly rate ($68) was applied to the 2012 time burden, the 2012 cost burden would have been $59,086,560.

[214] The annual public reporting burden for the CSP and PRC, excluding FSS vendors participating in the Transactional Data Reporting pilot, is $57.66 million. If FSS pilot vendors were still subject to the CSP and PRC reporting requirements, the total annual public reporting burden would be $101.69 million. The FSS pilot vendors' share of the total CSP and PRC reporting burden is based upon their share of the GSA FSS fiscal year 2015 sales volume, 43.2 percent. The annual $44.03 million reporting burden reduction attributed to this rule is 43.2 percent of the $101.69 million annual reporting burden if it were applied to the entire GSA FSS program. More information about Information Collection 3090–0235 can be found at *http://www.reginfo.gov/public* by searching "ICR" for "3090–0235".

[215] See GSAR Case 2013–G504; Docket 2014–0020; Sequence 1 (80 FR 11619 (Mar. 4, 2015)).

[216] $32 million does not include costs for non-FSS contracts. It is the result of the FSS burden of the initial pilot implementation ($12.41 million), minus the share of the combined CSP and PRC burden allocated to the FSS pilot vendors ($44.03 million). The total CSP and PRC burden from Information Collection 3090–0235, if it were applied to all GSA FSS vendors, including those participating in the Transactional Data Reporting pilot, would be $101.69 million. The share of that burden allocated to the FSS pilot vendors ($44.03 million) is based on the percentage of the overall FY15 FSS sales accounted for by the FSS pilot vendors (43.2 percent).

[217] $3 million is the result of the Government's annual burden for this rule ($2.34 million) minus the share of the combined CSP and PRC burden for the Government allocated to the FSS pilot contracts ($5.58 million).

SIA: Letter from Don Erickson, CEO, Security Industry Association, May 4, 2015.

List of Subjects in 48 CFR Parts 501, 515, 516, 538, and 552

Government procurement.

Dated: June 16, 2016.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Governmentwide Policy.

For the reasons described in the preamble, GSA amends 48 CFR parts 501, 515, 516, 538, and 552 as follows:

PART 501—GENERAL SERVICES ADMINISTRATION ACQUISITION REGULATION SYSTEM

■ 1. The authority citation for 48 CFR part 501 continues to read as follows:

Authority: 40 U.S.C. 121(c).

501.106 [Amended]

■ 2. Amend section 501.106 in the table, by—

■ a. Adding in numerical sequence, GSAR Reference "515.408" and its corresponding OMB Control Number "3090–0235";

■ b. Adding in numerical sequence, GSAR Reference "552.216–75" and its corresponding OMB Control Number "3090–0306";

■ c. Removing GSAR Reference "552.238–74" and its corresponding OMB Control Numbers "3090–0121" and "3090–0250"; and

■ d. Adding in numerical sequence, GSAR Reference "552.238–74" and its corresponding OMB Control Numbers "3090–0121" and "3090–0306".

PART 515—CONTRACT BY NEGOTIATION

■ 3. The authority citation for 48 CFR part 515 is revised to read as follows:

Authority: 40 U.S.C. 121(c).

■ 4. Amend section 515.408 by—

■ a. Revising the introductory text of paragraph (a), and paragraph (a)(2);

■ b. Revising the introductory text of paragraphs (b) and (c);

■ c. Revising paragraph (d); and

■ d. Revising the introductory text of paragraph (e) and paragraph (e)(1).

The revisions read as follows:

515.408 Solicitation provisions and contract clauses.

* * * * *

(a) Use Alternate IV of the FAR provision at 52.215–20, Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data, for MAS solicitations to provide the format for submission of information other than cost or pricing data for MAS solicitations. To provide uniformity in requests under the MAS program, insert the following in paragraph (b) of the provision:

* * * * *

(2) *Commercial sales practices.* When the solicitation contains the basic clause 552.238–74 Industrial Funding Fee and Sales Reporting, the Offeror must submit information in the format provided in this solicitation in accordance with the instructions at Figure 515.4–2 of the GSA Acquisition Regulation (48 CFR 515.4–2), or submit information in the Offeror's own format.

* * * * *

(b) When the contract contains the basic clause 552.238–74 Industrial Funding Fee and Sales Reporting, insert the following format for commercial sales practices in the exhibits or attachments section of the solicitation and resulting contract (see FAR 12.303).

* * * * *

(c) When the contract contains the basic clause 552.238–74 Industrial Funding Fee and Sales Reporting, include the instructions for completing the commercial sales practices format in Figure 515.4–2 in solicitations issued under the MAS program.

* * * * *

(d) When the contract contains the basic clause 552.238–74 Industrial Funding Fee and Sales Reporting, insert the clause at 552.215–72, Price Adjustment—Failure to Provide Accurate Information, in solicitations and contracts under the MAS program.

* * * * *

(e) Use Alternate IV of FAR 52.215–21, Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data—Modifications, to provide for submission of information other than cost or pricing data for MAS contracts. To provide for uniformity in requests under the MAS program, insert the following in paragraph (b) of the clause:

(1) Information required by the clause at 552.238–81, Modifications (Multiple Award Schedule).

* * * * *

PART 516—TYPES OF CONTRACTS

■ 5. The authority citation for 48 CFR part 516 continues to read as follows:

Authority: 40 U.S.C. 121(c).

■ 6. Amend section 516.506 by adding paragraph (d) to read as follows:

516.506 Solicitation provisions and contract clauses.

* * * * *

(d) The Contracting Officer may insert clause 552.216–75 in solicitations and GSA-awarded IDIQ contracts, not including Federal Supply Schedule (FSS) contracts. This clause should be included in all GSA-awarded Governmentwide acquisition contracts and multi-agency contracts. See 538.273 for clauses applicable to FSS contracts.

PART 538—FEDERAL SUPPLY SCHEDULE CONTRACTING

■ 7. The authority citation for 48 CFR part 538 continues to read as follows:

Authority: 40 U.S.C. 121(c).

■ 8. Revise section 538.270 to read as follows:

538.270 Evaluation of multiple award schedule (MAS) offers.

■ 9. Add section 538.270–1 to read as follows:

538.270–1 Evaluation of offers without access to transactional data.

(a) *Applicability.* Utilize this evaluation methodology for negotiating MAS offers when the commercial sales practices format is included in the solicitation (see 515.408).

(b) When offerors have commercial catalogs, negotiate concessions from established catalogs, including price and non-price terms and conditions.

(c) The Government will seek to obtain the offeror's best price (the best price given to the most favored customer). However, the Government recognizes that the terms and conditions of commercial sales vary and there may be legitimate reasons why the best price is not achieved.

(d) Establish negotiation objectives based on a review of relevant data and determine price reasonableness.

(e) When establishing negotiation objectives and determining price reasonableness, compare the terms and conditions of the MAS solicitation with the terms and conditions of agreements with the offeror's commercial customers. When determining the Government's price negotiation objectives, consider the following factors:

(1) Aggregate volume of anticipated purchases.

(2) The purchase of a minimum quantity or a pattern of historic purchases.

(3) Prices taking into consideration any combination of discounts and concessions offered to commercial customers.

(4) Length of the contract period.

(5) Warranties, training, and/or maintenance included in the purchase price or provided at additional cost to the product prices.

(6) Ordering and delivery practices.

(7) Any other relevant information, including differences between the MAS solicitation and commercial terms and conditions that may warrant differentials between the offer and the discounts offered to the most favored commercial customer(s). For example, an offeror may incur more expense selling to the Government than to the customer who receives the offeror's best price, or the customer (*e.g.*, dealer, distributor, original equipment manufacturer, other reseller) who receives the best price may perform certain value-added functions for the offeror that the Government does not perform. In such cases, some reduction in the discount given to the Government may be appropriate. If the best price is not offered to the Government, you should ask the offeror to identify and explain the reason for any differences. Do not require offerors to provide detailed cost breakdowns.

(f) You may award a contract containing pricing which is less favorable than the best price the offeror extends to any commercial customer for similar purchases if you make a determination that both of the following conditions exist:

(1) The prices offered to the Government are fair and reasonable, even though comparable discounts were not negotiated.

(2) Award is otherwise in the best interest of the Government.

(g) State clearly in the award document the price/discount relationship between the Government and the identified commercial customer (or category of customers) upon which the award is based.

■ 10. Amend section 538.271 by revising paragraph (a) and removing paragraph (c).

The revision reads as follows:

538.271 MAS contract awards.

(a) MAS awards will be for commercial items as defined in FAR 2.101.

* * * * *

■ 11. Revise section 538.272 to read as follows:

538.272 MAS price reductions.

(a) *Applicability.* This section applies when the contract contains the basic clause 552.238–74 Industrial Funding Fee and Sales Reporting.

(b) The basic clause and Alternate I of 552.238–75, Price Reductions, requires the contractor to maintain during the contract period the negotiated price/discount relationship (and/or term and condition relationship) between the eligible ordering activities and the offeror's customer or category of customers on which the contract award was predicated (see 538.271(c)). If a change occurs in the contractor's commercial pricing or discount arrangement applicable to the identified commercial customer (or category of customers) that results in a less advantageous relationship between the eligible ordering activities and this customer or category of customers, the change constitutes a "price reduction."

(c) Ensure that the contractor understands the requirements of section 552.238–75 and agrees to report all price reductions to the Contracting Officer as provided for in the clause.

■ 12. Amend section 538.273 by revising paragraph (b) to read as follows:

538.273 Contract clauses.

* * * * *

(b) *Multiple and single award schedules.* Insert the following in solicitations and contracts:

(1) *552.238–74, Industrial Funding Fee and Sales Reporting.* Use Alternate I for Federal Supply Schedules with Transactional Data Reporting requirements. Clause 552.238–75 Alternate II should also be used when vendors agree to include clause 552.238–74 Alternate I in the contract.

(2) *552.238–75, Price Reductions.* (i) Except in cases where Alternate II is used, use Alternate I in solicitations and contracts for—

(A) Federal Supply Schedule 70;

(B) The Consolidated Schedule containing information technology Special Item Numbers;

(C) Federal Supply Schedule 84; and

(D) Federal Supply Schedules for recovery purchasing (see 538.7102).

(ii) Use Alternate II for Federal Supply Schedules with Transactional Data Reporting requirements. This alternate clause is used when vendors agree to include clause 552.238–74 Alternate I in the contract.

(3) *552.238–81, Modifications (Federal Supply Schedule).* (i) Use Alternate I for Federal Supply Schedules that only accept electronic modifications.

(ii) Use Alternate II for Federal Supply Schedules with Transactional Data Reporting requirements. This alternate clause is used when vendors agree to include clause 552.238–74 Alternate I in the contract.

PART 552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 13. The authority citation for 48 CFR part 552 continues to read as follows:

Authority: 40 U.S.C. 121(c).

■ 14. Amend section 552.212–71 by revising the date of the clause and removing from paragraph (b) "__552.243–72 Modifications (Multiple Award Schedule)" and adding, in numerical sequence, "__552.238–81 Modifications (Multiple Award Schedule)". The revision reads as follows:

552.212–71 Contract Terms and Conditions Applicable to GSA Acquisition of Commercial Items.

* * * * *

Contract Terms and Conditions Applicable to GSA Acquisition of Commercial Items JUN 2016)

* * * * *

■ 15. Add section 552.216–75 to read as follows:

552.216–75 Transactional Data Reporting.

As prescribed in 516.506(d), insert the following provision:

Transactional Data Reporting (JUN 2016)

(a) *Definition. Transactional data* encompasses the historical details of the products or services delivered by the Contractor during the performance of task or delivery orders issued against this contract.

(b) *Reporting of Transactional Data.* The Contractor must report all transactional data under this contract as follows:

(1) The Contractor must electronically report transactional data by utilizing the automated reporting system at an Internet Web site designated by the General Services Administration (GSA) or by uploading the data according to GSA instructions. GSA will post registration instructions and reporting procedures on the Vendor Support Center Web site, *https://vsc.gsa.gov.* The reporting system Web site address, as well as registration instructions and reporting procedures, will be provided at the time of award or inclusion of this clause in the contract.

(2) The Contractor must provide, at no additional cost to the Government, the following transactional data elements, as applicable:

(i) Contract or Blanket Purchase Agreement (BPA) Number.

(ii) Delivery/Task Order Number/Procurement Instrument Identifier (PIID).

(iii) Non Federal Entity.

(iv) Description of Deliverable.

(v) Manufacturer Name.

(vi) Manufacturer Part Number.

(vii) Unit Measure (each, hour, case, lot).

(viii) Quantity of Item Sold.

(ix) Universal Product Code.

(x) Price Paid per Unit.

(xi) Total Price.

Note to paragraph (b)(2): The Contracting Officer may add data elements to the standard elements listed in paragraph (b)(2) of this section with the approvals listed in GSAM 507.105(c)(3).

(3) The Contractor must report transactional data within 30 calendar days from the last calendar day of the month. If there was no contract activity during the month, the Contractor must submit a confirmation of no reportable transactional data within 30 calendar days of the last calendar day of the month.

(4) The Contractor must report the price paid per unit, total price, or any other data elements with an associated monetary value listed in (b)(2) of this section, in U.S. dollars.

(5) The Contractor must maintain a consistent accounting method of transactional data reporting, based on the Contractor's established commercial accounting practice.

(6) *Reporting Points.* (i) The acceptable points at which transactional data may be reported include—

(A) Issuance of an invoice; or

(B) Receipt of payment.

(ii) The Contractor must determine whether to report transactional data on the basis of invoices issued or payments received.

(7) The Contractor must continue to furnish reports, including confirmation of no transactional data, through physical completion of the last outstanding task or delivery order issued against the contract.

(8) Unless otherwise expressly stated by the ordering activity, orders that contain classified information or other information that would compromise national security are exempt from this reporting requirement.

(9) This clause does not exempt the Contractor from fulfilling existing reporting requirements contained elsewhere in the contract.

(10) GSA reserves the unilateral right to change reporting instructions following 60 calendar days' advance notification to the Contractor.

(c) *Contract Access Fee (CAF).* (1) GSA's operating costs are reimbursed through a CAF charged on orders placed against this contract. The CAF is paid by the ordering activity but remitted to GSA by the Contractor. GSA has the unilateral right to change the fee structure at any time, but not more than once per year; GSA will provide reasonable notice prior to the effective date of any change.

(2) Within 60 calendar days of award or inclusion of this clause in the contract, a GSA representative will provide the Contractor with specific written procedural instructions on remitting the CAF, including the deadline by which the Contractor must remit the CAF. The deadline specified in the written procedural instructions will be no less than 30 calendar days after the last calendar day of the month. GSA reserves the unilateral right to change remittance instructions following 60 calendar days' advance notification to the Contractor.

(3) The Contractor must remit the CAF to GSA in U.S. dollars.

(4) The Contractor's failure to remit the full amount of the CAF within the specified deadline constitutes a contract debt to the United States Government under the terms of FAR Subpart 32.6. The Government may exercise all rights under the Debt Collection Improvement Act of 1996, including withholding or offsetting payments and interest on the debt (see FAR clause 52.232–17, Interest). If the Contractor fails to submit the required sales reports, falsifies them, or fails to timely pay the CAF, these reasons constitute sufficient cause for the Government to terminate the contract for cause.

(End of Provision)

■ 16. Amend section 552.238–74 by adding Alternate I to read as follows:

552.238–74 Industrial Funding Fee and Sales Reporting.

* * * * *

Alternate I ([Insert abbreviated month and year of publication in the ***Federal Register****.]):* As prescribed in 538.273(b)(1), substitute the following paragraphs (a), (b), (c), and (d) for paragraphs (a), (b), (c), and (d) of the basic clause:

(a) *Definition. Transactional data* encompasses the historical details of the products or services delivered by the Contractor during the performance of task or delivery orders issued against this contract.

(b) *Reporting of Transactional Data.* The Contractor must report all transactional data under this contract as follows:

(1) The Contractor must electronically report transactional data by utilizing the automated reporting system at an Internet Web site designated by the General Services Administration (GSA) or by uploading the data according to GSA instructions. GSA will post registration instructions and reporting procedures on the Vendor Support Center Web site, *https://vsc.gsa.gov.* The reporting system Web site address, as well as registration instructions and reporting procedures, will be provided at the time of award or inclusion of this clause in the contract.

(2) The Contractor must provide, at no additional cost to the Government, the following transactional data elements, as applicable:

(i) Contract or Blanket Purchase Agreement (BPA) Number.

(ii) Delivery/Task Order Number/ Procurement Instrument Identifier (PIID).

(iii) Non Federal Entity.

(iv) Description of Deliverable.

(v) Manufacturer Name.

(vi) Manufacturer Part Number.

(vii) Unit Measure (each, hour, case, lot).

(viii) Quantity of Item Sold.

(ix) Universal Product Code.

(x) Price Paid per Unit.

(xi) Total Price.

Note to paragraph (b)(2): The Contracting Officer may add data elements to the standard elements listed in paragraph (b)(2) of this section with the approvals listed in GSAM 507.105(c)(3).

(3) The contractor must report transactional data within 30 calendar days from the last calendar day of the month. If there was no contract activity during the month, the Contractor must submit a confirmation of no reportable transactional data within 30 calendar days of the last calendar day of the month.

(4) The Contractor must report the price paid per unit, total price, or any other data elements with an associated monetary value listed in (b)(2) of this section, in U.S. dollars.

(5) The reported price paid per unit and total price must include the Industrial Funding Fee (IFF).

(6) The Contractor must maintain a consistent accounting method of transactional data reporting, based on the Contractor's established commercial accounting practice.

(7) *Reporting Points.* (i) The acceptable points at which transactional data may be reported include—

(A) Issuance of an invoice; or

(B) Receipt of payment.

(ii) The Contractor must determine whether to report transactional data on the basis of invoices issued or payments received.

(8) The Contractor must continue to furnish reports, including confirmation of no transactional data, through physical completion of the last outstanding task or delivery order of the contract.

(9) Unless otherwise expressly stated by the ordering activity, orders that contain classified information or other or information that would compromise national security are exempt from this reporting requirement.

(10) This clause does not exempt the Contractor from fulfilling existing

reporting requirements contained elsewhere in the contract.

(11) GSA reserves the unilateral right to change reporting instructions following 60 calendar days' advance notification to the Contractor.

(c) *Industrial Funding Fee (IFF).* (1) This contract includes an IFF charged on orders placed against this contract. The IFF is paid by the authorized ordering activity but remitted to GSA by the Contractor. The IFF reimburses GSA for the costs of operating the Federal Supply Schedule program, as set forth in 40 U.S.C. 321: Acquisition Services Fund. Net operating revenues generated by the IFF are also applied to fund initiatives benefitting other authorized GSA programs, in accordance with 40 U.S.C. 321.

(2) GSA has the unilateral right to change the fee amount at any time, but not more than once per year; GSA will provide reasonable notice prior to the effective date of any change. GSA will post notice of the current IFF on the Vendor Support Center Web site at *https://vsc.gsa.gov.*

(3) Offerors must include the IFF in their prices. The fee is included in the awarded price(s) and reflected in the total amount charged to ordering activities. The fee will not be included in the price of non-contract items purchased pursuant to a separate contracting authority, such as a Governmentwide Acquisition Contract (GWAC); a separately awarded Federal Acquisition Regulation (FAR) Part 12, FAR Part 13, FAR Part 14, or FAR Part 15 procurement; or a non-FAR contract.

(4) The Contractor must remit the IFF to GSA in U.S. dollars within 30 calendar days after the last calendar day of the reporting quarter; final payment must be remitted within 30 calendar days after physical completion of the last outstanding task order or delivery order issued against the contract.

(5) GSA reserves the unilateral right to change remittance instructions following 60 calendar days' advance notification to the Contractor.

(d) The Contractor's failure to remit the full amount of the IFF within 30 calendar days after the end of the applicable reporting period constitutes a contract debt to the United States Government under the terms of FAR Subpart 32.6. The Government may exercise all rights under the Debt Collection Improvement Act of 1996, including withholding or offsetting payments and interest on the debt (see FAR clause 52.232–17, Interest). If the Contractor fails to submit the required transactional data reports, falsifies them, or fails to timely pay the IFF, these reasons constitute sufficient cause for the Government to terminate the contract for cause.

■ 17. Amend section 552.238–75 by adding Alternate II to read as follows:

552.238–75 Price Reductions.

* * * * *

Alternate II ([Insert abbreviated month and year of publication in the ***Federal Register****.]).* As prescribed in 538.273(b)(2)(ii), substitute the following paragraphs (a) and (b) for paragraphs (a), (b), (c), (d), (e), (f) and (g) of the basic clause:

(a) The Government may request from the Contractor, and the Contractor may provide to the Government, a temporary or permanent price reduction at any time during the contract period.

(b) The Contractor may offer the Contracting Officer a voluntary price reduction at any time during the contract period.

■ 18. Amend section 552.238–81 by—

■ a. In Alternate I, revising the date of the alternate and the introductory text; and

■ b. Adding Alternate II.

The revisions and addition read as follows:

552.238–81 Modification (Federal Supply Schedule).

* * * * *

Alternate I ([Insert abbreviated month and year of publication in the ***Federal Register****.]).* As prescribed in 538.273(b)(3)(i), add the following paragraph (f) to the basic clause:

* * * * *

Alternate II ([Insert abbreviated month and year of publication in the ***Federal Register****.]).* As prescribed in 538.273(b)(3)(ii), substitute the following paragraph (b) for paragraph (b) of the basic clause:

(b) *Types of Modifications.*

(1) *Additional items/additional SINs.* When requesting additions, the Contractor must submit the following information:

(i) Information about the new item(s) or the item(s) under the new SIN(s) must be submitted in accordance with the instructions in the solicitation.

(ii) Delivery time(s) for the new item(s) or the item(s) under the new SIN(s) must be submitted in accordance with the request for proposal.

(iii) Production point(s) for the new item(s) or the item(s) under the new SIN(s) must be submitted if required by FAR 52.215–6, Place of Performance.

(iv) Hazardous Material information (if applicable) must be submitted as required by FAR 52.223–3 (Alternate I), Hazardous Material Identification and Material Safety Data.

(v) Any information requested by FAR 52.212–3(f), Offeror Representations and Certifications-Commercial Items, that may be necessary to assure compliance with FAR 52.225–1, Buy American Act-Balance of Payments Programs-Supplies.

(2) *Deletions.* The Contractor must provide an explanation for the deletion. The Government reserves the right to reject any subsequent offer of the same item or a substantially equal item at a higher price during the same contract period, if the Contracting Officer determines that the higher price is unreasonable compared to the price of the deleted item.

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Part V

Securities and Exchange Commission

In the Matter of the Application of: Investors' Exchange, LLC for Registration as a National Securities Exchange; Findings, Opinion, and Order of the Commission; Notices

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78101; File No. 10–222]

In the Matter of the Application of: Investors' Exchange, LLC for Registration as a National Securities Exchange; Findings, Opinion, and Order of the Commission

June 17, 2016.

I. Introduction and Procedural History

On August 21, 2015, Investors' Exchange, LLC ("IEX" or "IEX Exchange") submitted to the Securities and Exchange Commission ("Commission") a Form 1 application ("Form 1") under the Securities Exchange Act of 1934 ("Act"), seeking registration as a national securities exchange pursuant to Section 6 of the Act.[1] IEX has amended its Form 1 five times, as detailed below. The Commission has reviewed the exchange registration application, as amended, together with all comments received, in order to make a determination whether to grant the registration.[2]

On September 9, 2015, IEX submitted Amendment No. 1 to its Form 1.[3] Notice of the application, as amended by Amendment No. 1, was published for comment in the **Federal Register** on September 22, 2015.[4] On December 18, 2015, IEX consented to an extension of time to March 21, 2016 for Commission consideration of its Form 1 application and the comments received thereon.[5] In response to comments, IEX submitted an amendment to its Form 1 on February 29, 2016 to propose a new approach to outbound routing, which had been the subject of extensive public comment as originally proposed.[6] IEX submitted a third amendment to its Form 1 on March 4, 2016.[7] IEX submitted a fourth amendment to its Form 1 on March 7, 2016.[8] IEX submitted a fifth amendment to its Form 1 on May 27, 2016.[9] All together, the Commission received 474 comments regarding the IEX Exchange Form 1.[10] IEX submitted several responses to comments.[11]

On March 18, 2016, the Commission issued an order ("Order Instituting Proceedings" or "OIP") that provided public notice of the significant changes IEX proposed to its application in Amendment Nos. 2, 3, and 4, and solicited comment on the amended Form 1, while simultaneously instituting proceedings under Section 19(a)(1)(B) of the Act[12] to determine whether to grant or deny IEX's exchange registration application, as amended.[13] By publishing notice of, and soliciting comment on, IEX's Form 1, as amended by Amendment Nos. 2, 3, and 4, and simultaneously instituting proceedings, the Commission sought public input in particular on whether IEX's proposed new outbound routing structure, as reflected by IEX's Form 1 and rules as amended by Amendment Nos. 2, 3, and 4 is consistent with the Act, and accordingly, whether IEX should be registered as a national securities exchange.[14] The Order Instituting Proceedings extended until June 18, 2016, the date by which the Commission shall grant or deny IEX's Form 1, as amended, for registration as a national securities exchange. The Commission received additional comment on IEX's amended Form 1 subsequent to the publication of the Order Instituting Proceedings. A list of the comments received on IEX's Form 1 is set forth in Appendix A.

For the reasons set forth below, and based on the representations set forth in IEX's Form 1, as amended, as supplemented in IEX's responses to comments included in the public comment file, this order approves IEX's Form 1 application, as amended, for registration as a national securities exchange.

II. Statutory Standards

Pursuant to Sections 6(b) and 19(a) of the Act,[15] the Commission shall by order grant an application for registration as a national securities exchange if the Commission finds, among other things, that the proposed exchange is so organized and has the capacity to carry out the purposes of the Act and can comply, and can enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the rules of the exchange.

As discussed in greater detail below, the Commission finds that IEX Exchange's application, as amended, for exchange registration meets the requirements of the Act and the rules and regulations thereunder. Further, the Commission finds that the proposed rules of IEX Exchange are consistent with Section 6 of the Act in that, among other things, they are designed to: (1) Assure fair representation of the exchange's members in the selection of its directors and administration of its affairs and provide that, among other things, one or more directors shall be representative of investors and not be associated with the exchange, or with a broker or dealer; [16] (2) prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, and remove impediments to and perfect the mechanisms of a free and open market and a national market system; [17] (3) not permit unfair discrimination between customers, issuers, or dealers; [18] and (4) protect investors and the public interest.[19] The Commission also finds that the rules of IEX Exchange are consistent with Section 11A of the Act.[20] Finally, the Commission finds that IEX Exchange's proposed rules at this time do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[21]

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[1] 15 U.S.C. 78f.

[2] *See* 15 U.S.C. 78f and 15 U.S.C. 78s.

[3] In Amendment No. 1, IEX submitted updated portions of its Form 1, including revised exhibits, a revised version of the proposed IEX Rule Book, and revised Addenda C–2, C–3, C–4, D–1, D–2, F–1, F–2, F–3, F–4, F–5, F–6, F–7, F–8, F–9, F–10, F–11, F–12, F–13.

[4] *See* Securities Exchange Act Release No. 75925 (September 15, 2015), 80 FR 57261 ("Notice").

[5] *See* Letter from Sophia Lee, General Counsel, IEX, to Brent J. Fields, Secretary, Commission, dated December 18, 2015.

[6] In Amendment No. 2, IEX proposed changes to its Form 1 to, among other things, redesign its outbound routing functionality to direct routable orders first to the IEX routing logic instead of directly to the IEX matching engine. *See* Letter from Sophia Lee, General Counsel, IEX, to Brent J. Fields, Secretary, Commission, dated February 29, 2016, at 1. In this manner, the IEX router would "interact with the IEX matching system over a 350 microsecond speed-bump in the same way an independent third party broker would be subject to a speed bump." *Id.*

[7] In Amendment No. 3, IEX proposed changes to its Form 1 to clarify and correct revisions to its rulebook that it made in Amendment No. 2. *See* Letter from Sophia Lee, General Counsel, IEX, to Brent J. Fields, Secretary, Commission, dated March 4, 2016.

[8] In Amendment No. 4, IEX proposed changes to its Form 1 to update Exhibit E to reflect changes it proposed in Amendment No. 2. *See* Letter from Sophia Lee, General Counsel, IEX, to Brent J. Fields, Secretary, Commission, dated March 7, 2016.

[9] In Amendment No. 5, IEX updated Exhibits J and K to reflect changes since its initial filing. *See* Letter from Sophia Lee, General Counsel, IEX, to Brent J. Fields, Secretary, Commission, dated May 27, 2016.

[10] *See* Appendix A (listing comments received on this matter).

[11] *See* Letter from Sophia Lee, General Counsel, IEX, to Brent J. Fields, Secretary, Commission, dated November 13, 2015 ("IEX First Response"); Letter from Sophia Lee, General Counsel, IEX, to Brent J. Fields, Secretary, Commission, dated November 23, 2015 ("IEX Second Response"); Letter from Sophia Lee, General Counsel, IEX, to Brent J. Fields, Secretary, Commission, dated February 9, 2016 ("IEX Third Response"); Letter from Donald Bollerman, Head of Markets and Sales, IEX Group, Inc., to File No. 10–222, dated February 16, 2016 ("IEX Fourth Response"); Letter from IEX Group, Inc., to File No. 10–222, dated February 19, 2016 ("IEX Fifth Response"); and Letter from Sophia Lee, General Counsel, IEX, to Brent J. Fields, Secretary, Commission, dated February 29, 2016 ("IEX Sixth Response").

[12] 15 U.S.C. 78s(a)(1)(B).

[13] *See* Securities Exchange Act Release No. 77406, 81 FR 15765 (March 24, 2016) (File No. 10–222) ("Order Instituting Proceedings" or "OIP"). Also on March 18, 2016, the Commission separately issued a notice of a proposed Commission interpretation regarding automated quotations under Regulation NMS. *See* Securities Exchange Act Release No. 77407, 81 FR 15660 (March 24, 2016) (File No. S7–03–16) ("Notice of Proposed Interpretation"). Separately, today, the Commission has adopted a final interpretation. *See* Securities Exchange Act Release No. 78102 (June 17, 2016) (File No. S7–03–16) ("Final Interpretation").

[14] While IEX's proposed outbound routing structure was one focus of the Commission's solicitation of comment in the Order Instituting Proceedings, it is but one of several aspects of IEX's Form 1 that the Commission must consider in determining whether to grant or deny IEX's exchange registration application. All such aspects are discussed below.

[15] 15 U.S.C. 78f(b) and 15 U.S.C. 78s(a), respectively.

III. Discussion

A. Governance of IEX Exchange [22]

IEX Group, Inc. ("IEXG"), a Delaware corporation, will own 100% of IEX Exchange as well as IEX Services LLC ("IEXS"), a registered broker-dealer that currently operates an alternative trading system ("IEX ATS"). Following the launch of operations of IEX Exchange, IEXS would be a facility of IEX Exchange and would provide outbound order routing services to IEX Exchange.[23]

1. IEX Exchange Board of Directors

The board of directors of IEX Exchange ("Exchange Board") will be its governing body and will possess all of the powers necessary for the management of its business and affairs, including governance of IEX Exchange as a self-regulatory organization ("SRO").[24]

Under the Amended and Restated Operating Agreement of Investors' Exchange LLC ("IEX Exchange Operating Agreement"): [25]

- The Exchange Board will initially be composed of seven directors; [26]
- One director will be the Chief Executive Officer of IEX Exchange;[27]
- The number of Non-Industry Directors,[28] including at least two Independent Directors,[29] will equal or exceed the sum of the number of Industry Directors [30] and Member Representative Directors; [31]
- At least twenty percent of the directors on the Exchange Board will be Member Representative Directors; [32] and
- A majority of the Board of Directors will be Independent Directors.[33]

In addition, during such time as IEX Exchange operates a listings business, the Exchange Board must have one Director who is an officer or director of an issuer and one Director who is a representative of investors, and in each case, such Director must not be associated with a member.[34]

As discussed further below, the initial Directors of the Exchange Board shall be appointed by IEXG and shall serve until the first annual meeting of holders of LLC interests of Investors' Exchange LLC, of which IEX Group, Inc. is the sole holder ("LLC Member"). In its Form 1 application, IEX committed to hold its first annual meeting as a registered exchange within 90 days after the date of final action by the Commission on IEX's application for registration as a national securities exchange ("Approval Date").[35] At the first annual meeting of the LLC Member and each annual meeting thereafter, IEXG, as the sole LLC Member of IEX Exchange, will elect the Exchange Board pursuant to the IEX Exchange Operating Agreement and consistent with the compositional requirements specified therein.[36] In addition, IEXG will appoint the initial Nominating Committee [37] and Member Nominating Committee,[38] consistent with each committee's compositional requirements,[39] to nominate candidates for election to the Exchange Board. Each of the Nominating Committee and Member Nominating Committee, after completion of its respective duties for nominating directors for election to the Board for that year, shall nominate candidates to serve on the succeeding year's Nominating Committee or Member Nominating Committee, as applicable, such candidates to be voted on by IEXG at the annual meeting of the LLC Member.[40] IEX Exchange members have rights to nominate and elect additional candidates for the Member Nominating Committee pursuant to a petition process.[41]

The Nominating Committee will nominate candidates for each director position, and IEXG, as the sole LLC Member, will elect those directors. For Member Representative Director positions, the Member Nominating Committee will solicit input from IEX members and members may submit petition candidates.[42] If no candidates are nominated pursuant to a petition process, then the initial nominees submitted by the Member Nominating Committee will be nominated as Member Representative Directors by the Nominating Committee. If a petition process produces additional candidates, then the candidates nominated pursuant to the petition process, together with those nominated by the Member Nominating Committee, will be presented to IEX Exchange members for election to determine the final nominees for any open Member Representative Director positions.[43] In the event of a contested election, the candidates who receive the most votes will be selected as the Member Representative Director nominees by the Nominating Committee.[44]

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[16] *See* 15 U.S.C. 78f(b)(3).

[17] *See* 15 U.S.C. 78f(b)(5).

[18] *See id.*

[19] *See id.*

[20] 15 U.S.C. 78k–1.

[21] 15 U.S.C. 78f(b)(8).

[22] The Commission did not receive any comments addressing the substance of the governance provisions.

[23] *See* Form 1, Exhibit C. *See also* IEX Exchange Rule 2.220.

[24] *See* IEX Exchange Operating Agreement, Article III, Section 1.

[25] *See* Form 1, Exhibit A–3.

[26] *See* IEX Exchange Operating Agreement, Article III, Section 2(a).

[27] *See* IEX Exchange Operating Agreement, Article III, Section 2(b).

[28] "Non-Industry Director" means a Director who is an Independent Director or any other individual who would not be an Industry Director. *See* IEX Exchange Operating Agreement, Article I(x).

[29] "Independent Director" means a "Director who has no material relationship with the [IEX Exchange] or any affiliate of the [IEX Exchange], or any [IEX member] or any affiliate of any such [IEX member]; *provided*, however, that an individual who otherwise qualifies as an Independent Director shall not be disqualified from serving in such capacity solely because such Director is a Director of the [IEX Exchange] or [IEXG]." *See* IEX Exchange Operating Agreement, Article I(n).

[30] Generally, an "Industry Director" is, among other things, a Director that is or has been within the prior three years an officer, director, employee, or owner of a broker or dealer, as well as any Director who has, or has had, a consulting or employment relationship with IEX Exchange or any affiliate of IEX Exchange within the prior three years. *See* IEX Exchange Operating Agreement Article I(p). This definition is consistent with what the Commission has approved for other exchanges. *See, e.g.,* Securities Exchange Act Release Nos. 62716 (August 13, 2010), 75 FR 51295 (August 19, 2010) ("BATS Y Exchange Order"); and 68341 (December 3, 2012), 77 FR 73065 (December 7, 2012) ("MIAX Exchange Order").

[31] *See* IEX Exchange Operating Agreement, Article III, Section 2(b). "Member Representative Director" means a Director who has been appointed by IEXG as an initial Director pursuant to Article III, Section 4(g) of the IEX Exchange Operating Agreement to serve until the first annual meeting or who has been "elected by the LLC Member after having been nominated by the Member Nominating Committee or by an Exchange Member pursuant to [the] Operating Agreement and confirmed as the nominee of Exchange Members after majority vote of Exchange Members, if applicable. A Member Representative Director must be an officer, director, employee, or agent of an Exchange Member that is not a Stockholder Exchange Member." *See* IEX Exchange Operating Agreement, Article I(u). *See also* IEX Exchange Operating Agreement, Article III, Section 4(g).

[32] *See* IEX Exchange Operating Agreement, Article III, Section 2(b).

[33] *See id.*

[34] *See id.*

[35] *See* IEX Exchange Operating Agreement, Article III, Section 4(g). *See also* discussion of "Interim Exchange Board" *infra.*

[36] *See* IEX Exchange Operating Agreement, Article IV, Section 1(a).

[37] The number of Non-Industry members on the Nominating Committee must equal or exceed the number of Industry members. All Nominating Committee members must be Independent Directors. *See* IEX Exchange Operating Agreement Article VI, Section 2. *See also* IEX Exchange Operating Agreement Article V, Section 2(a).

[38] Each member of the Member Nominating Committee shall be a Member Representative member. *See* IEX Exchange Operating Agreement Article VI, Section 3. *See also* IEX Exchange Operating Agreement Article V, Section 2(a). Pursuant to IEX Exchange Operating Agreement Article I(v), a "Member Representative member" is a member of any committee or hearing panel who is an officer, director, employee or agent of an Exchange Member that is not a Stockholder Exchange Member.

[39] *See* IEX Exchange Operating Agreement Article VI, Section 1.

[40] *See id.*

[41] *See id. See also* IEX Exchange Operating Agreement Article III, Section 4.

Thereafter, the Member Nominating Committee will nominate a final slate of candidates to the Nominating Committee, and the Nominating Committee must accept those candidates and submit them to the LLC Member.[45] IEXG, as the sole LLC Member, is obligated to elect the Member Representative Director nominees that are nominated by the Nominating Committee.[46]

In addition, with respect to the requirement that the number of Non-Industry Directors, including at least two Independent Directors, will equal or exceed the sum of the number of Industry Directors and Member Representative Directors, the Commission believes that the proposed composition of the Exchange Board satisfies the requirements in Section 6(b)(3) of the Act,[47] which requires in part that one or more directors be representative of issuers and investors and not be associated with a member of the exchange, or with a broker or dealer. The Commission previously has stated that the inclusion of public, non-industry representatives on exchange oversight bodies is an important mechanism to support an exchange's ability to protect the public interest.[48] Further, the presence of public, non-industry representatives can help to ensure that no single group of market participants has the ability to systematically disadvantage other market participants through the exchange governance process.[49] The Commission believes that public directors can provide unbiased perspectives, which may enhance the ability of the Exchange Board to address issues in a non-discriminatory fashion and foster the integrity of IEX Exchange.[50] For similar reasons, the Commission also believes that the additional compositional requirement that applies during such time as IEX Exchange operates a primary listings business (*i.e.*, the requirement that one Director be an officer or director of an issuer and one Director be a representative of investors, in each case, not associated with a Member[51]) is consistent with the requirements of Section 6(b)(3) of the Act.

The Commission believes that the IEX Exchange governance provisions are consistent with the Act. In particular, the Commission believes that the requirement in the IEX Exchange Operating Agreement that 20% of the directors be Member Representative Directors and the means by which they will be chosen by IEX Exchange members provide for the fair representation of members in the selection of directors and the administration of IEX Exchange and therefore are consistent with Section 6(b)(3) of the Act.[52] As the Commission has previously noted, this requirement helps to ensure that members have a voice in an exchange's self-regulatory program, and that an exchange is administered in a way that is equitable to all those who trade on its market or through its facilities.[53]

2. Interim Exchange Board

IEXG will appoint an interim Exchange board of directors ("Interim Exchange Board") at a special meeting, which will include interim Member Representative Directors. The interim Member Representative Directors will be selected by the Buy-Side Trading Advisory Committee ("TAC") of IEXG from a list of potential candidates submitted by current subscribers of the IEX ATS.[54] IEX represents that these IEX ATS subscribers are expected to become members of IEX Exchange through submission of and approval of an Exchange Waive-In Membership Application.[55] IEX also represents that it currently expects that the Exchange's initial membership would consist substantially of the current group of IEX ATS subscribers, including, but not limited to, those IEX ATS subscribers that have submitted potential candidates to the TAC, and that it does not expect to receive a meaningful number of applications for Exchange membership from non-IEX ATS subscribers during the tenure of the Interim Exchange Board.[56] Upon the appointment of the interim directors by IEXG, the Interim Exchange Board will meet the board composition requirements set forth in the IEX Exchange Operating Agreement.[57]

The Interim Exchange Board will serve until the first annual meeting of the LLC Member, which will take place within 90 days after the Approval Date, when the Exchange Board will be elected pursuant to the full nomination, petition, and voting process set forth in the IEX Exchange Operating Agreement.[58] IEX represents that it will complete the full nomination, petition, and voting process set forth in the IEX Exchange Operating Agreement as promptly as possible after the effective date of the IEX Exchange Operating Agreement and within ninety (90) days after the Approval Date.[59]

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[42] *See* IEX Exchange Operating Agreement Article III, Section 4(c). The petition must be signed by executive representatives of 10% or more of the IEX Exchange members. No IEX Exchange member, together with its affiliates, may account for more than 50% of the signatures endorsing a particular candidate. *See id.*

[43] *See* IEX Exchange Operating Agreement, Article III, Section 4(e) and (f). Each IEX Exchange Member shall have the right to cast one vote for each available Member Representative Director nomination, provided that any such vote must be cast for a person on the List of Candidates and that no IEX Exchange member, together with its affiliates, may account for more than 20% of the votes cast for a candidate. *See* IEX Exchange Operating Agreement, Article III, Section 4(f).

[44] *See* IEX Exchange Operating Agreement, Article III, Section 4(f).

[45] *See* IEX Exchange Operating Agreement, Article III, Section 4(a). The Member Nominating Committee will solicit comments from IEX Exchange members for the purpose of approving and submitting names of candidates for election to the position of Member Representative Director. *See* IEX Exchange Operating Agreement, Article III, Section 4(b).

[46] *See id.*

[47] 15 U.S.C. 78f(b)(3).

[48] *See, e.g.*, Regulation of Exchanges and Alternative Trading Systems, Securities Exchange Act Release No. 40760 (December 8, 1998), 63 FR 70844 (December 22, 1998) ("Regulation ATS Release").

[49] *See, e.g.*, MIAX Exchange Order, *supra* note 30, at 73067.

[50] *See, e.g.*, Securities Exchange Act Release No. 53128 (January 13, 2006), 71 FR 3550, 3553 (January 23, 2006) (granting the exchange registration of Nasdaq Stock Market, Inc.) ("Nasdaq Exchange Order"); Securities Exchange Act Release No. 53382 (February 27, 2006), 71 FR 11251, 11261 (March 6, 2006) ("NYSE/Archipelago Merger Approval Order"); and BATS Y Exchange Order, *supra* note 30 at 51298.

[51] *See* IEX Exchange Operating Agreement, Article III, Section 2(b).

[52] 15 U.S.C. 78f(b)(3).

[53] *See, e.g.*, Nasdaq Exchange Order, *supra* note 50; and BATS Y Exchange Order, *supra* note 30. *See also* NYSE/Archipelago Merger Approval Order, *supra* note 50.

[54] *See* Form 1, Exhibit J.

[55] *See id.*

[56] *See id.*

[57] *See id.*

[58] *See id. See also* IEX Exchange Operating Agreement, Article III, Section 4.

[59] *See* Form 1, Exhibit J.

The Commission believes that the process for electing the Interim Exchange Board, as proposed, is consistent with the requirements of the Act, including that the rules of the exchange assure fair representation of the exchange's members in the selection of its directors and administration of its affairs.[60] As noted above, the interim Member Representative Directors will be selected by IEXG from a list of potential candidates submitted by a group of current subscribers of the IEX ATS. IEX expects its IEX ATS subscribers to become the initial members of IEX Exchange and does not expect significant numbers of new members initially, and therefore conducting the initial Member Representative Director process among these entities is an appropriate way to put in place promptly at IEX's launch as an exchange a board with Member Representative directors that represent the exchange's initial membership. The Commission notes that this Interim Exchange Board is only temporary, as IEX Exchange represents that it will complete the full nomination, petition, and voting process as set forth in the IEX Exchange Operating Agreement, which will provide persons that are approved as members after the date of this Order with the opportunity to participate in the selection of the Member Representative Directors, within 90 days of when IEX Exchange's application for registration as a national securities exchange is granted.[61] The Commission therefore believes that IEX Exchange's initial interim board process is consistent with the Act, including Section 6(b)(3), in that it is designed to provide representation among the persons and firms likely to become members when IEX commences operations as an exchange and is sufficient to allow IEX to commence operations as an exchange for an interim period prior to going through the regular process to elect a new Exchange Board pursuant to the full nomination, petition, and voting process set forth in the IEX Exchange Operating Agreement.

3. Exchange Committees

In the IEX Exchange Operating Agreement, IEX Exchange has proposed to establish several committees of the Exchange Board. Specifically, IEX Exchange has proposed to establish the following committees of the Exchange Board that would be appointed by the Chairman of the Exchange Board, with the approval of the Exchange Board: An Appeals Committee and a Regulatory Oversight Committee.[62] In addition, IEX Exchange has proposed to establish a Nominating Committee and a Member Nominating Committee, which would be elected on an annual basis by IEXG, as the sole LLC Member.[63] Further, the IEX Chairman, with approval of the Exchange Board, may appoint a Compensation Committee, an Audit Committee, an Executive Committee, and a Finance Committee of the Exchange Board.[64]

The Appeals Committee will consist of two Independent Directors, and one Member Representative Director.[65] Each member of the Regulatory Oversight Committee must be an Independent Director.[66] If established, each voting member of the Compensation Committee must be a Non-Industry Director.[67] If established, a majority of the Audit Committee members must be Non-Industry Directors, all Audit Committee Directors must be Independent Directors, and a Non-Industry Director will serve as Chairman.[68]

Because the Executive Committee will have the powers and authority of the Exchange Board in the management of the business and affairs of the IEX Exchange between meetings of the Exchange Board, its composition must reflect that of the Exchange Board. Accordingly, if established, the number of Non-Industry Directors on the Executive Committee must equal or exceed the number of Industry Directors and the percentages of Independent Directors and Member Representative Directors must be at least as great as the corresponding percentages on the Exchange Board as a whole.[69]

As discussed above, the Nominating and Member Nominating Committees will have responsibility for, among other things, nominating candidates for election to the Exchange Board. On an annual basis, the members of these committees will nominate candidates for the succeeding year's respective committees to be elected by IEXG, as the sole LLC Member.[70]

The Commission believes that IEX Exchange's proposed committees, which are similar to the committees maintained by other exchanges,[71] are designed to help enable IEX Exchange to carry out its responsibilities under the Act and are consistent with the Act, including Section 6(b)(1), which requires, in part, an exchange to be so organized and have the capacity to carry out the purposes of the Act.[72]

B. IEX Group and Regulation of IEX Exchange[73]

When IEX Exchange commences operations as a national securities exchange, IEX Exchange will have all the attendant regulatory obligations under the Act. In particular, IEX Exchange will be responsible for the operation and regulation of its trading system and the regulation of its members. The Commission believes that certain provisions in the IEX Exchange and IEXG governance documents are designed to facilitate the ability of IEX Exchange and the Commission to fulfill their regulatory obligations. The discussion below summarizes some of these key provisions.

1. Ownership Structure; Ownership and Voting Limitations

IEX Exchange will be structured as a Delaware limited liability company ("LLC"), which will be wholly owned by the sole member of the LLC, IEXG. The proposed Third Amended and Restated Certificate of Incorporation of IEX Group, Inc. ("IEXG Certificate") includes restrictions on the ability to own and vote shares of capital stock of IEXG.[74] These limitations are designed to prevent any IEXG shareholder from exercising undue control over the operation of IEX Exchange and to ensure that the IEX Exchange and the

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[60] *See* 15 U.S.C. 78f(b)(3).

[61] IEX's proposed timeline for the interim board process follows a process similar to what the Commission recently approved for the MIAX Exchange. *See* MIAX Exchange Order, *supra* note 30.

[62] *See* IEX Exchange Operating Agreement, Article V, Section 1.

[63] *See* IEX Exchange Operating Agreement Article VI, Section 1.

[64] *See* IEX Exchange Operating Agreement Article V, Section 6.

[65] *See* IEX Exchange Operating Agreement Article V, Section 6(d).

[66] *See* IEX Exchange Operating Agreement Article V, Section 6(c).

[67] *See* IEX Exchange Operating Agreement Article V, Section 6(a).

[68] *See* IEX Exchange Operating Agreement Article V, Section 6(b).

[69] *See* IEX Exchange Operating Agreement Article V, Section 6(e).

[70] *See* IEX Exchange Operating Agreement Article VI, Section 1. Additional candidates for the Member Nominating Committee may be nominated and elected by IEX Exchange members pursuant to a petition process. *See supra* note 42 and accompanying text.

[71] *See, e.g.,* BATS Y Exchange Order and MIAX Exchange Order, *supra* note 30.

[72] 15 U.S.C. 78f(b)(1).

[73] The Commission did not receive any comments addressing the substance of regulation.

[74] These provisions are consistent with ownership and voting limits approved by the Commission for other SROs. *See e.g.,* BATS Y Exchange Order and MIAX Exchange Order, *supra* note 30. *See also* Securities Exchange Act Release Nos. 61698 (March 12, 2010), 75 FR 13151 (March 18, 2010) ("DirectEdge Exchanges Order"); and 58375 (August 18, 2008) 73 FR 49498 (August 21, 2008) (File No. 10–182) ("BATS Exchange Order").

Commission are able to carry out their regulatory obligations under the Act.

In particular, for so long as IEXG directly or indirectly controls IEX Exchange, no person, either alone or together with its related persons,[75] may beneficially own more than 40% of any class of capital stock of IEXG.[76] IEX will have a more restrictive condition for IEX Exchange members, wherein IEX Exchange members, either alone or together with their related persons, are prohibited from beneficially owning more than 20% of shares of any class of capital stock of IEXG.[77] If any stockholder violates these ownership limits, IEXG would redeem the shares in excess of the applicable ownership limit at their par value.[78] In addition, no person, alone or together with its related persons, may vote or cause the voting of more than 20% of the voting power of the then issued and outstanding capital stock of IEXG.[79] If any stockholder purports to vote, or cause the voting of, shares that would violate this voting limit, IEXG would not honor such vote in excess of the voting limit.[80]

Any person that proposes or attempts to own shares of capital stock in excess of the 40% ownership limitation, or vote or grant proxies or consents with respect to shares of capital stock in excess of the 20% voting limitation, must deliver written notice to the IEXG board of directors ("IEXG Board") to notify the IEXG Board of its intention.[81] The notice must be delivered to the IEXG Board not less than 45 days before the proposed ownership of such shares or proposed exercise of such voting rights or the granting of such proxies or consents.[82] The IEXG Board may waive the 40% ownership limitation and the 20% voting limitation for non-members, pursuant to a resolution duly adopted by the IEXG Board, if it makes certain findings.[83] The IEXG Board is specifically prohibited from waiving the voting and ownership limits above 20% for IEX Exchange members and their related persons.[84] As required by the IEXG Certificate, any waiver for non-members would not be effective unless and until approved by the Commission pursuant to Section 19 of the Act.[85]

The IEXG Certificate also contains provisions that are designed to further safeguard the ownership and voting limitations described above, or are otherwise related to direct and indirect changes in control. Specifically, any person that, either alone or together with its related persons owns, directly or indirectly, of record or beneficially, 5% or more of the capital stock of IEXG will be required to immediately notify the IEXG Board in writing upon acquiring knowledge of such ownership.[86] Thereafter, such persons will be required to update IEXG of any increase or decrease of 1% or more in their previously reported ownership percentage.[87]

The IEX Exchange Operating Agreement does not include change of control provisions that are similar to those in the IEXG Certificate; however the IEX Exchange Operating Agreement explicitly provides that IEXG is the sole LLC Member of IEX Exchange.[88] Thus, if IEXG ever proposes to no longer be the sole LLC Member of IEX Exchange (and therefore no longer its sole owner), IEX Exchange would be required to amend the IEX Exchange Operating Agreement. Any changes to the IEX Exchange Operating Agreement, including any change in the provisions that identify IEXG as the sole owner of IEX Exchange, would be a rule change that must be filed with, or filed with and approved by, the Commission pursuant to Section 19(b) of the Act and Rule 19b–4.[89] Further, pursuant to the IEX Exchange Operating Agreement, IEXG may not transfer or assign, in whole or in part, its ownership interest in IEX Exchange, unless such transfer or assignment is filed with and approved by the Commission pursuant to Section 19 of the Act.[90]

Although IEXG is not directly responsible for regulation, its activities with respect to the operation of IEX Exchange must be consistent with, and must not interfere with, the self-regulatory obligations of IEX Exchange. As described above, the provisions applicable to direct and indirect changes in control of IEXG and IEX Exchange, as well as the voting limitation imposed on owners of IEXG who also are IEX Exchange members, are designed to help prevent any owner of IEXG from exercising undue influence or control over the operation of IEX Exchange and to help ensure that IEX Exchange retains a sufficient degree of independence to effectively carry out its regulatory obligations under the Act. In addition, these limitations are designed to address the conflicts of interests that might result from a member of a national securities exchange owning interests in the exchange. As the Commission has noted in the past, a member's ownership interest in an entity that controls an exchange could become so large as to cast doubt on whether the exchange may fairly and objectively exercise its self-regulatory responsibilities with respect to such member.[91] A member that is a controlling shareholder of an exchange could seek to exercise that controlling influence by directing the exchange to refrain from, or the exchange may hesitate to, diligently monitor and conduct surveillance of the member's conduct or diligently enforce the exchange's rules and the federal securities laws with respect to conduct by the member that violates such provisions. As such, the Commission believes that these requirements are designed to minimize the potential that a person or entity can improperly interfere with or restrict the ability of IEX Exchange to effectively carry out its regulatory oversight responsibilities under the Act.

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[75] *See* IEXG Certificate TENTH (A)(2) (defining "related persons").

[76] *See* IEXG Certificate TENTH (B)(1.1).

[77] *See* IEXG Certificate TENTH (B)(1.2).

[78] *See* IEXG Certificate TENTH (E). Any shares which have been called for redemption shall not be deemed outstanding shares for the purpose of voting or determining the total number of shares entitled to vote. Once redeemed by IEXG, such shares shall become treasury shares and shall no longer be deemed to be outstanding. *See id.* Furthermore, if any redemption results in another stockholder owning shares in violation of the ownership limits described above, IEXG shall redeem such shares. *See id.*

[79] *See* IEXG Certificate TENTH (B)(1.3).

[80] *See* IEXG Certificate TENTH (D).

[81] *See* IEXG Certificate TENTH (B)(4).

[82] *See id.*

[83] *See* IEXG Certificate TENTH (B)(2.2). The required determinations are that (A) such waiver will not impair the ability of IEX Exchange to carry out its functions and responsibilities under the Act and the rules and regulations promulgated thereunder, (B) such waiver is otherwise in the best interests of IEXG, its stockholders, and IEX Exchange, (C) such waiver will not impair the ability of the Commission to enforce the Act and the rules and regulations promulgated thereunder, and (D) the transferee in such transfer and its related persons are not subject to any applicable "statutory disqualification" (within the meaning of Section 3(a)(39) of the Act). *See* IEXG Certificate TENTH (B)(2.2) and (B)(3). The Commission has previously approved identical rules of other exchanges that provide for the ability of the exchange to waive the ownership and voting limitations discussed above for non-members of the exchange. *See, e.g.,* BATS Y Exchange Order, *supra* note 30 at 51296; and MIAX Exchange Order, *supra* note 30 at 73069. *See also* Amended and Restated Certificate of Incorporation of Miami International Holdings, Inc. Article Ninth(b)(ii)(B) and (iii); and Amended and Restated Certificate of Incorporation of BATS Global Markets, Inc. Article Fifth(b)(ii)(B) and (iii) (containing identical provisions).

[84] *See* IEXG Certificate TENTH (B)(2.2) (". . . and such resolution shall not be effective until it is filed with and approved by the Commission."). These provisions are generally consistent with waiver of ownership and voting limits approved by the Commission for other SROs. *See e.g.,* BATS Y Exchange Order and MIAX Exchange Order, *supra* note 30. *See also* BATS Exchange Order and DirectEdge Exchanges Order, *supra* note 74.

[85] *See* IEXG Certificate TENTH (B)(2.2).

[86] *See* IEXG Certificate TENTH(C)(1). The notice will require the person's full legal name; the person's title or status; the person's approximate ownership interest in IEXG; and whether the person has power, directly or indirectly, to direct the management or policies of IEXG. *See id.*

[87] *See* IEXG Certificate TENTH(C)(2). Changes of less than 1% must also be reported to IEXG if they result in such person crossing a 20% or 40% ownership threshold. *See id.* In addition, IEX Exchange rules also impose limits on affiliation between the IEX Exchange and a member of the IEX Exchange. *See* IEX Exchange Rule 2.210 (No Affiliation between Exchange and any Member).

[88] *See* IEX Exchange Operating Agreement Article I(s).

[89] *See* IEX Exchange Operating Agreement, Article IX, Section 1(b) and Section 4. *See also* 15 U.S.C. 78s(b) and 17 CFR 240.19b–4.

[90] *See* IEX Exchange Operating Agreement Article IV, Section 4 and Article XI, Section 12.

[91] *See, e.g.,* BATS Y Exchange Order and MIAX Exchange Order, *supra* note 30.

The Commission believes that IEX's and IEXG's proposed governance provisions are consistent with the Act, including Section 6(b)(1), which requires, in part, an exchange to be so organized and have the capacity to carry out the purposes of the Act.[92] In particular, these requirements are designed to minimize the potential that a person could improperly interfere with or restrict the ability of the Commission or IEX Exchange to effectively carry out their regulatory oversight responsibilities under the Act.

2. Regulatory Independence and Oversight

Although IEXG will not itself carry out regulatory functions, its activities with respect to the operation of IEX Exchange must be consistent with, and must not interfere with, IEX Exchange's self-regulatory obligations. In this regard, IEX Exchange and IEXG propose to adopt certain provisions in their respective governing documents that are designed to help maintain the independence of the regulatory functions of IEX Exchange. These proposed provisions are substantially similar to those included in the governing documents of other exchanges that recently have been granted registration.[93] Specifically:

- The directors, officers, employees, and agents of IEXG must give due regard to the preservation of the independence of the self-regulatory function of IEX Exchange and to its obligations to investors and the general public and must not take actions that would interfere with the effectuation of decisions by the Exchange Board relating to its regulatory functions or that would interfere with IEX Exchange's ability to carry out its responsibilities under the Act.[94]
- IEXG must comply with federal securities laws and the rules and regulations promulgated thereunder, and agrees to cooperate with the Commission and IEX Exchange pursuant to, and to the extent of, their respective regulatory authority. In addition, IEXG's officers, directors, employees, and agents must comply with federal securities laws and the rules and regulations promulgated thereunder and are deemed to agree to cooperate with the Commission and IEX Exchange in respect of the Commission's oversight responsibilities regarding IEX Exchange and the self-regulatory functions and responsibilities of IEX Exchange and IEXG shall take reasonable steps necessary to cause its officers, directors, employees and agents to so cooperate.[95]
- IEXG, and its officers, directors, employees, and agents submit to the jurisdiction of the U.S. federal courts, the Commission, and IEX Exchange, for purposes of any action, suit, or proceeding pursuant to U.S. federal securities laws, and the rules and regulations thereunder, arising out of, or relating to, IEX Exchange activities.[96]
- All books and records of IEX Exchange reflecting confidential information pertaining to the self-regulatory function of IEX Exchange (including but not limited to disciplinary matters, trading data, trading practices, and audit information) shall be retained in confidence by IEX Exchange and its personnel, including its directors, officers, employees and agents, and will not be used by IEX Exchange for any non-regulatory purposes and shall not be made available to any person (including, without limitation, any IEX Exchange member) other than to personnel of the Commission, and those personnel of IEX Exchange, members of committees of the Exchange Board, members of the Exchange Board, or hearing officers and other agents of IEX Exchange, to the extent necessary or appropriate to properly discharge the self-regulatory responsibilities of IEX Exchange.[97] Similar provisions apply to IEXG and its directors, officers, employees and agents.[98]
- The books and records of IEX Exchange and IEXG must be maintained in the United States[99] and, to the extent they are related to the operation or administration of IEX Exchange, IEXG's books and records will be subject at all times to inspection and copying by the Commission and IEX Exchange.[100]
- Furthermore, to the extent they relate to the activities of IEX Exchange, the books, records, premises, officers, directors, employees, and agents of IEXG will be deemed to be the books, records, premises, officers, directors, employees, and agents of IEX Exchange, for purposes of, and subject to oversight pursuant to, the Act.[101]
- IEXG will take reasonable steps necessary to cause its officers, directors, employees, and agents, prior to accepting a position as an officer, director, employee or agent (as applicable) to consent in writing to the applicability of provisions regarding books and records, confidentiality, jurisdiction, and regulatory obligations, with respect to their activities related to IEX Exchange.[102]
- The IEXG Certificate and By-Laws require that, so long as IEXG controls IEX Exchange, any changes to those documents must be submitted to the

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[92] 15 U.S.C. 78f(b)(1).

[93] *See, e.g.,* MIAX Exchange Order and BATS Y Order, *supra* note 30. *See also* DirectEdge Exchanges Order, *supra* note 74.

[94] *See* proposed Amended and Restated By-Laws of IEX Group, Inc. ("IEXG By-Laws"), Article VII, Section 34. Similarly, Article III, Section 1(d) of the IEX Exchange Operating Agreement requires the Exchange Board and each Director to, when managing the business and affairs of IEX Exchange, consider the requirements of Section 6(b) of the Act. Article III, Section 1(e) also requires the Exchange Board, when evaluating any proposal to take into account (among other things and to the extent relevant), the potential impact on the integrity, continuity and stability of the national securities exchange operated by IEX Exchange and the other operations of IEX Exchange, on the ability to prevent fraudulent and manipulative acts and practices, and on investors and the public, and whether such would promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to and facilitating transactions in securities or assist in the removal of impediments to or perfection of the mechanisms for a free and open market and a national market system.

[95] *See* IEXG By-Laws, Article VII, Section 37. Similarly, Article III, Section 1(d) of the IEX Exchange Operating Agreement requires IEX Exchange's directors, officers and employees, in discharging their duties, to comply with the federal securities laws and the rules and regulations promulgated thereunder and to cooperate with the Commission and IEX Exchange pursuant to their respective regulatory authority.

[96] *See* IEXG By-Laws, Article VII, Section 38.

[97] *See* IEX Exchange Operating Agreement Article XI, Section 4.

[98] The IEXG By-Laws also provide that all books and records of IEX Exchange reflecting confidential information pertaining to the self-regulatory function of IEX Exchange that come into the possession of IEXG, and the information contained in those books and records, will be subject to confidentiality restrictions and will not be used for any non-regulatory purposes. *See* IEXG By-Laws Article VII, Section 35. The IEXG governing documents acknowledge that requirements to keep such information confidential shall not limit or impede the rights of the Commission to access and examine such information or limit the ability of officers, directors, employees, or agents of IEX Exchange or IEXG to disclose such information to the Commission. *See* IEX Exchange Operating Agreement Article XI, Section 4 and IEXG By-Laws Article VII, Section 35.

[99] *See* IEX Exchange Operating Agreement Article XI, Section 4; and IEXG By-Laws Article VII, Section 36.

[100] *See* IEXG By-Laws Article VII, Section 36.

[101] *See* IEXG By-Laws Article VII, Section 36.

[102] *See* IEXG By-Laws Article VII, Section 39.

Exchange Board for approval, and, if such change is required to be filed with the Commission pursuant to Section 19(b) of the Act and the rules and regulations thereunder, such change shall not be effective until filed with and effective by operation of law, or filed with, and approved by, the Commission.[103]

The Commission believes that the provisions discussed in this section, which are designed to help ensure the independence of IEX Exchange's regulatory function and facilitate the ability of IEX Exchange to carry out its responsibility and operate in a manner consistent with the Act, are appropriate and consistent with the requirements of the Act, particularly with Section 6(b)(1), which requires, in part, an exchange to be so organized and have the capacity to carry out the purposes of the Act.[104] Whether IEX Exchange operates in compliance with the Act, however, depends on how it and IEXG in practice implement the governance and other rules that are the subject of this Order.

Further, Section 19(h)(1) of the Act[105] provides the Commission with the authority "to suspend for a period not exceeding twelve months or revoke the registration of [an SRO], or to censure or impose limitations upon the activities, functions, and operations of [an SRO], if [the Commission] finds, on the record after notice and opportunity for hearing, that [the SRO] has violated or is unable to comply with any provision of the Act, the rules or regulations thereunder, or its own rules or without reasonable justification or excuse has failed to enforce compliance . . ." with any such provision by its members (including associated persons thereof).[106] If the Commission were to find, or become aware of, through staff review and inspection or otherwise, facts indicating any violations of the Act, including without limitation Sections 6(b)(1) and 19(g)(1), these matters could provide the basis for a disciplinary proceeding under Section 19(h)(1) of the Act.

The Commission also notes that, even in the absence of the governance provisions described above, under Section 20(a) of the Act any person with a controlling interest in IEX Exchange would be jointly and severally liable with and to the same extent that IEX Exchange is liable under any provision of the Act, unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.[107] In addition, Section 20(e) of the Act creates aiding and abetting liability for any person who knowingly provides substantial assistance to another person in violation of any provision of the Act or rule thereunder.[108] Further, Section 21C of the Act authorizes the Commission to enter a cease-and-desist order against any person who has been "a cause of" a violation of any provision of the Act through an act or omission that the person knew or should have known would contribute to the violation.[109] These provisions are applicable to all entities' dealings with IEX Exchange, including IEXG.

3. Regulatory Oversight Committee

The regulatory operations of IEX Exchange will be monitored by the Regulatory Oversight Committee of the Exchange Board. The Regulatory Oversight Committee will consist of at least two members, all of whom must be Independent Directors. The Regulatory Oversight Committee will be responsible for overseeing the adequacy and effectiveness of IEX Exchange's regulatory and SRO responsibilities, assessing IEX Exchange's regulatory performance, and assisting the Exchange Board (and committees of the Exchange Board) in reviewing IEX Exchange's regulatory plan and the overall effectiveness of IEX Exchange's regulatory functions.[110]

Further, a Chief Regulatory Officer ("CRO") of IEX Exchange will have general supervision over IEX Exchange's regulatory operations, including responsibility for overseeing IEX Exchange's surveillance, examination, and enforcement functions and for administering any regulatory services agreements with another self-regulatory organization to which IEX Exchange is a party.[111] The Regulatory Oversight Committee, in consultation with the Chief Executive Officer of IEX Exchange, will be responsible for establishing the goals, assessing the performance, and fixing the compensation of the Chief Regulatory Officer and for recommending personnel actions involving the Chief Regulatory Officer and senior regulatory personnel.[112]

4. Regulatory Funding and Services

As a prerequisite for the Commission's granting of an exchange's application for registration, an exchange must be organized and have the capacity to carry out the purposes of the Act.[113] Specifically, an exchange must be able to enforce compliance by its members, and persons associated with its members, with the federal securities laws and rules thereunder and the rules of the exchange.[114] The discussion below summarizes how IEX Exchange proposes to conduct and structure its regulatory operations.

a. Regulatory Funding

To help ensure that IEX has and will continue to have adequate funding to be able to meet its responsibilities under the Act, IEX Exchange represents that, if the Commission approves IEX's application for registration as a national securities exchange, IEXG will allocate sufficient assets to IEX Exchange to enable the exchange's operation.[115] Specifically, IEX Exchange represents that IEXG will make a cash contribution to IEX Exchange of $5,000,000, in addition to any previously-provided in-kind contributions, such as legal, regulatory, and infrastructure-related services.[116]

IEX Exchange also represents that such cash and in-kind contributions from IEXG will be adequate to operate IEX Exchange, including the regulation of the exchange, and that IEXG and IEX Exchange will enter into an agreement that requires IEXG to provide adequate funding over time for the exchange's operations, including the regulation of IEX Exchange.[117]

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[103] *See* IEXG Certificate Article NINTH; and IEXG By-Laws, Article XIV, Section 51.

[104] 15 U.S.C. 78f(b)(1).

[105] *See* 15 U.S.C. 78s(h)(1).

[106] *Id.*

[107] 15 U.S.C. 78t(a).

[108] 15 U.S.C. 78t(e).

[109] 15 U.S.C. 78u–3.

[110] *See* IEX Exchange Operating Agreement Article V, Section 6(c). The Regulatory Oversight Committee is responsible for reviewing IEX Exchange's regulatory budget, and also will meet regularly with the Chief Regulatory Officer. *See id.*

[111] *See* IEX Exchange Operating Agreement Article VII, Section 9.

[112] *See* IEX Exchange Operating Agreement Article V, Section 6(c). To the extent that the Chief Executive Officer of IEX Exchange has any indirect supervisory responsibility for the role or function of the CRO, including but not limited to, implementation of the budget for the regulatory function or regulatory personnel matters, the Regulatory Oversight Committee will take all steps reasonably necessary to ensure that the Chief Executive Officer does not compromise the regulatory autonomy and independence of the CRO or the regulatory function. *See id.*

[113] *See* Section 6(b)(1) of the Act, 15 U.S.C. 78f(b)(1).

[114] *See id. See also* Section 19(g) of the Act, 15 U.S.C. 78s(g).

[115] *See* Form 1, Exhibit I.

[116] *See id.*

[117] *See id.* IEX Exchange represents that this agreement will provide that IEX Exchange receive all fees, including regulatory fees and trading fees, payable by IEX Exchange's members, as well as any funds received from any applicable market data fees and tape revenue, and will further provide that IEXG will reimburse IEX Exchange for its costs and expenses to the extent the exchange's assets are insufficient to meet its costs and expenses. *Id.*

Further, any "Regulatory Funds" received by IEX Exchange will not be used for non-regulatory purposes or distributed to IEXG, but rather will be applied to fund the regulatory operations of IEX Exchange, or, as applicable, used to pay restitution and disgorgement to customers as part of a regulatory proceeding.[118] Any excess non-regulatory funds, as determined by IEX Exchange, may be remitted to IEXG.[119]

b. Regulatory Contract With FINRA

Although IEX Exchange will be an SRO with all of the attendant regulatory obligations under the Act, it has represented to the Commission that it intends to enter into a Regulatory Services Agreement ("RSA") with FINRA, under which FINRA will perform certain regulatory functions on IEX Exchange's behalf.[120] Specifically, IEX Exchange represents that FINRA will perform certain regulatory surveillance of trading activity on IEX Exchange and conduct various regulatory services on behalf of IEX Exchange, which are expected to include performance of investigation, disciplinary, and hearing services.[121] Notwithstanding the RSA, IEX Exchange will retain legal responsibility for the regulation of its members and its market and the performance of FINRA as its regulatory services provider. Because IEX Exchange anticipates entering into an RSA with FINRA, it has not made provisions to fulfill the regulatory services that would be undertaken by FINRA. Accordingly, the Commission is conditioning the operation of IEX Exchange on IEX Exchange and FINRA entering into a final RSA that specifies the services that FINRA will provide to IEX Exchange.

The Commission believes that it is consistent with the Act for IEX Exchange to contract with FINRA to perform certain examination, enforcement, and disciplinary functions.[122] These functions are fundamental elements of a regulatory program, and constitute core self-regulatory functions. The Commission believes that FINRA has the expertise and experience to perform these functions for IEX Exchange.[123] However, IEX Exchange, unless relieved by the Commission of its responsibility, bears the self-regulatory responsibilities and primary liability for self-regulatory failures, not the SRO retained to perform regulatory functions on IEX Exchange's behalf.[124] In performing these regulatory functions, however, FINRA may nonetheless bear liability for causing or aiding and abetting the failure of IEX Exchange to perform its regulatory functions.[125] Accordingly, although FINRA will not act on its own behalf under its SRO responsibilities in carrying out these regulatory services for IEX Exchange, FINRA may have secondary liability if, for example, the Commission finds that the contracted functions are being performed so inadequately as to cause a violation of the federal securities laws or rules thereunder by IEX Exchange.[126]

c. 17d–2 Agreements

Section 19(g)(1) of the Act,[127] among other things, requires every SRO registered as either a national securities exchange or national securities association to examine for, and enforce compliance by, its members and persons associated with its members with the Act, the rules and regulations thereunder, and the SRO's own rules, unless the SRO is relieved of this responsibility pursuant to Section 17(d) or Section 19(g)(2) of the Act.[128] Rule 17d–2 of the Act permits SROs to propose joint plans to allocate regulatory responsibilities amongst themselves for their common rules with respect to their common members.[129] These agreements, which must be filed with and declared effective by the Commission, generally cover areas where each SRO's rules substantively overlap, including such regulatory functions as personnel registration and sales practices. Without this relief, the statutory obligation of each individual SRO could result in a pattern of multiple examinations of broker-dealers that maintain memberships in more than one SRO.[130] Such regulatory duplication would add unnecessary expenses for common members and their SROs.[131]

A 17d–2 plan that is declared effective by the Commission relieves the specified SRO of those regulatory responsibilities allocated by the plan to another SRO.[132] Many SROs have entered into Rule 17d–2 agreements.[133] IEX has represented to the Commission that IEX Exchange and FINRA intend to file a 17d–2 agreement with the Commission covering common members of IEX Exchange and FINRA.[134] This agreement would allocate to FINRA regulatory responsibility, with respect to common members, for specified regulatory and enforcement matters arising out of specified common rules and specified provisions of the Act and the rules and regulations thereunder. In addition, IEX Exchange has represented to the Commission that it intends to become a party to the existing multiparty Rule 17d–2 plan for the surveillance, investigation, and enforcement of common insider trading rules.[135]

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[118] *See* IEX Exchange Operating Agreement Article X, Section 4. IEX Exchange Operating Agreement Article I(zz) defines "Regulatory Funds" as "fees, fines, or penalties derived from the regulatory operations of the [IEX Exchange]," but such term does not include "revenues derived from listing fees, market data revenues, transaction revenues, or any other aspect of the commercial operations of the [IEX Exchange], even if a portion of such revenues are used to pay costs associated with the regulatory operations of the [IEX Exchange]." This definition of is consistent with the rules of other SROs. *See e.g.,* By-Laws of MIAX Exchange, Article 1(ee); By-Laws of NASDAQ PHLX LLC, Article I(ii); and By-Laws of NASDAQ BX, Inc., Article I(ii).

[119] *See* Form 1, Exhibit I. *See also* IEX Exchange Operating Agreement, Article XI, Section 5. Further, IEX Exchange will not be required to make a distribution to IEXG if such distribution would violate the Act or any other applicable law. *See id.*

[120] *See* Form 1, Exhibits C and L. *See also* IEX Exchange Rules 1.160(hh) and 6.170.

[121] *See* Form 1, Exhibit C.

[122] *See, e.g.,* Regulation ATS Release, *supra* note 48. *See also* Nasdaq Exchange Order, *supra* note 50; and BATS Exchange Order and DirectEdge Exchanges Order, *supra* note 74.

[123] *See, e.g.,* BATS Y Exchange Order, *supra* note 30; DirectEdge Exchanges Order, *supra* note 74; and Nasdaq Exchange Order, *supra* note 50. The Commission notes that the RSA is not before the Commission and, therefore, the Commission is not acting on it.

[124] *See* Section 19(g) of the Act, 15 U.S.C. 78s(g); and Section 17(d)(1) of the Act and Rule 17d–2 thereunder, 15 U.S.C. 78q(d)(1) and 17 CFR 240.17d–2, respectively. *See also infra* notes 127–135 and accompanying text.

[125] For example, if failings by FINRA have the effect of leaving IEX Exchange in violation of any aspect of IEX Exchange's self-regulatory obligations, IEX Exchange would bear direct liability for the violation, while FINRA may bear liability for causing or aiding and abetting the violation. *See, e.g.,* Nasdaq Exchange Order, *supra* note 50; BATS Exchange Order, *supra* note 74; and DirectEdge Exchange Order, *supra* note 74.

[126] *See, e.g.,* Nasdaq Exchange Order, *supra* note 50.

[127] 15 U.S.C. 78s(g)(1).

[128] 15 U.S.C. 78q(d) and 15 U.S.C. 78s(g)(2), respectively.

[129] *See* Section 17(d)(1) of the Act and Rule 17d–2 thereunder, 15 U.S.C. 78q(d)(1) and 17 CFR 240.17d–2, respectively. Section 17(d)(1) of the Act allows the Commission to relieve an SRO of certain responsibilities with respect to members of the SRO who are also members of another SRO ("common members"). Specifically, Section 17(d)(1) allows the Commission to relieve an SRO of its responsibilities to: (i) Receive regulatory reports from such members; (ii) examine such members for compliance with the Act and the rules and regulations thereunder, and the rules of the SRO; or (iii) carry out other specified regulatory responsibilities with respect to such members. Section 17(d) was intended, in part, to eliminate unnecessary multiple examinations and regulatory duplication with respect common members. *See* Securities Exchange Act Release No. 12935 (October 28, 1976), 41 FR 49091 (November 8, 1976) ("Rule 17d–2 Adopting Release").

[130] *See, e.g.,* Securities Exchange Act Release No. 76998 (January 29, 2016), 81 FR 6066, 6074 (ISE Mercury exchange order).

[131] *See id.*

[132] *See* Rule 17d–2 Adopting Release, *supra* note 129.

[133] *See, e.g.,* Securities Exchange Act Release Nos. 59218 (January 8, 2009), 74 FR 2143 (January 14, 2009) (File No. 4–575) (FINRA/Boston Stock Exchange, Inc.); 58818 (October 20, 2008), 73 FR 63752 (October 27, 2008) (File No. 4–569) (FINRA/BATS Exchange, Inc.); 55755 (May 14, 2007), 72 FR 28057 (May 18, 2007) (File No. 4–536) (National Association of Securities Dealers, Inc. ("NASD") (n/k/a FINRA) and CBOE concerning the CBOE Stock Exchange); 55367 (February 27, 2007), 72 FR 9983 (March 6, 2007) (File No. 4–529) (NASD/ISE); and 54136 (July 12, 2006), 71 FR 40759 (July 18, 2006) (File No. 4–517) (NASD/Nasdaq).

[134] *See* Form 1, Exhibit C.

Because IEX Exchange anticipates entering into these 17d–2 agreements, it has not made provision to fulfill the regulatory obligations that would be undertaken by FINRA and other SROs under these agreements with respect to common members.[136] Accordingly, the Commission is conditioning the operation of IEX Exchange on approval by the Commission of a 17d–2 agreement between IEX Exchange and FINRA that allocates the above specified matters to FINRA, and the approval of an amendment to the existing multiparty Rule 17d–2 agreement specified above to add IEX Exchange as a party.

C. IEX Trading System

Numerous comment letters the Commission received on IEX's Form 1 application focused on IEX's proposed trading rules and the operation of its system. Much of the public comment centered on issues related to specific features of IEX's proposed trading system—namely, its "Point-of-Presence" ("POP") and "coil" infrastructure (sometimes referred to as IEX's "speed bump") and the manner in which IEX originally proposed (prior to Amendment Nos. 2, 3, and 4) to provide outbound routing services through its affiliated routing broker-dealer. IEX submitted several response letters to address these issues before amending its Form 1 in Amendment Nos. 2, 3, and 4 to propose a fundamentally different approach to outbound routing. As detailed in the Order Instituting Proceedings, in these amendments IEX proposed a material change to its approach to outbound routing through its affiliated routing broker-dealer. In the Order Instituting Proceedings, the Commission provided public notice of IEX's amendments and solicited commenters' views as to whether IEX's proposed revisions, including the changes to its outbound routing functionality, were consistent with the Act. The outbound routing issue, other issues related to IEX's POP and coil infrastructure, and other issues that are relevant to IEX's proposed trading system in the context of the Commission's consideration of IEX's Form 1 are addressed below.

1. Public Comment Overview and Commission Discussion

The Commission received letters in support,[137] as well as letters opposing or criticizing in whole or part some of IEX's proposed features.[138] Among the commenters who supported IEX's Form 1, most argued that IEX would offer a market solution to address certain market inefficiencies and conflicts of interest in a manner that is intended to protect the interests of retail and buy-side investors.[139] In particular, though IEX did not propose any fees in its Form 1, commenters noted IEX's stated intent not to pursue "maker-taker" pricing and instead offer flat transaction fees.[140] Some commenters praised IEX for offering fewer order types.[141] Several commenters highlighted IEX's "coil" delay, discussed in detail below, and asserted that it may help counter latency arbitrage.[142] In addition, one commenter believed that the coil delay as initially proposed should not be grounds for denying IEX's exchange application, and suggested that IEX be phased into the national market system under a pilot program so that the effect of IEX's access delay on the wider market could be better assessed.[143]

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[135] *See id. See also* Securities Exchange Act Release No. 65991 (December 16, 2011), 76 FR 79714 (December 22, 2011) (File No. 4–566) (notice of filing and order approving and declaring effective an amendment to the multiparty 17d–2 plan relating to the surveillance, investigation, and enforcement of insider trading rules).

[136] The Commission notes that regulation that is to be covered by the 17d–2 agreement for common members will be carried out by FINRA under the RSA for IEX Exchange members that are not also members of FINRA.

[137] *See, e.g.,* Leuchtkafer First Letter; Leuchtkafer Second Letter; Verret Letter; Shatto Letters 1, 2, and 3; Simonelis Letter; Capital Group Letter; Southeastern Letter; Navari Letter; DV Advisors Letter; Cowen Letter; Themis First Letter; Themis Second Letter; Oppenheimer Funds Letter; Murphy Letter; Birch Bay Letter; Healthy Markets Letter; Keblish Letter; Bowcott Letter; Secrist Letter; Stevens Letter; Oltean Letter; Park Letter; Crespo Letter; Colbert Letter; Lewis Letter; Hovanec First Letter; Hovanec Second Letter; Meskill Letter; Brian S. Letter; Glennon Letter; Shaw Letter; Upson Letter; Goldman Sachs Letter; Robeson Letter; Lynch Letter; Budish Letter; Chen & Foley Letter; Liquidnet Letter; T. Rowe Price Letter; Sherman Letter; CALSTRS Letter; PSRS/PEERS Letter; Asset Owners/Investment Managers March 21 Letter; Maqbool Letter; Israel Letter.

[138] *See, e.g.,* BATS First Letter; BATS Second Letter; BATS Third Letter; NYSE First Letter; NYSE Second Letter; NYSE Third Letter; Nasdaq First Letter; Nasdaq Second Letter; Nasdaq Third Letter; Citadel First Letter; Citadel Second Letter; Citadel Third Letter; Citadel Fourth Letter; Citadel Fifth Letter; FIA First Letter; FIA Second Letter; Hudson River Trading First Letter; Hudson River Trading Second Letter; Anonymous December 5 Letter; Hunsacker Letter; Modern Markets Initiative Letter; Tabb Letter; Weldon First Letter; Markit First Letter; Markit Second Letter; Direct Match Letter; Duffy Letter; Scott Letter; Loh Letter; Anonymous June 16 Letter.

[139] *See, e.g.,* Capital Group Letter at 1 (noting the "technologies and practices to discourage predatory behavior" including the "350 microsecond buffer," the lack of maker-taker pricing, and "simple order types"); Southeastern Letter (submitted on behalf of a group of undersigned asset managers) (complimenting IEX's proposed benefits to investors in "reducing structural inefficiencies in the market, and offering a more balanced and simplified market design"); Navari Letter at 1 (noting certain features that "have great promise for the [r]etail [i]nvestor"); DV Advisors Letter; Cowen Letter; Themis First Letter (noting that IEX's "unconflicted investor-friendly alternative" will "employ technology designed to even playing fields, rather than exploit information asymmetry" and that IEX will be "a stark alternative to other stock exchange models that seem to be more focused on selling speed and data," and noting that as an ATS, IEX allowed it and its customers "to achieve best execution"); Oppenheimer Funds Letter; Murphy Letter (arguing that IEX's design should "help to limit and even eliminate" what it characterized as "the electronic front running that is central to the problems in the market today"); Lewis Letter; Keblish Letter; Secrist Letter; Stevens Letter; Oltean Letter; Meskill Letter; fi360 Letter; TRS Letter; Lynch Letter; Jefferies Letter; T. Rowe Price Letter; Liquidnet Letter; Sherman Letter; Anonymous March 18 Letter (group of anonymous traders noting that they "have empirically found IEX orders to lower transactions costs" relative to other exchanges); Israel Letter (noting that IEX's 350 microsecond delay is "explicitly designed to . . . level the playing field for ordinary investors"). One supportive commenter focused on the fee structure for the IEX ATS, asserting that it is simple and thus favors investors and issuers rather than traders seeking arbitrage profits. *See* ModernIR Letter at 1–3. This commenter also asserts that trades in the IEX ATS generally are not "offset by predatory activity," which "offers a beneficial environment to the money public companies seek: long-term committed capital." *See id.* at 1. Some commenters questioned the motive of other commenters, including exchanges, who opposed the proposal. *See* Verret Letter at 2 (arguing that "incumbent firms have long sought to utilize regulatory barriers to entry to minimize competition, and it would appear a number of firms are presently using the regulatory comment process regarding IEX's application as a venue to replicate that strategy here"); Shatto Letter 2 at 1 (noting that the critical commenters "do not represent investors or institutional investors" in arguing that "the SEC does not have to preserve market advantages for these people"); Shatto Letter 3; Stevens Letter; Crespo Letter; Meskill Letter; Brian S. Letter; Hovanec Third Letter; Hovanec Fourth Letter; Hovanec Sixth Letter; Hovanec Seventh Letter.

[140] *See, e.g.,* Capital Group Letter; Southeastern Letter; Navari First Letter; Navari Second Letter; Themis First Letter; Oppenheimer Funds Letter; Healthy Markets Letter; Abel/Noser Letter; Goldman Sachs Letter; Liquidnet Letter; Franklin Templeton Investments Letter; TRS Letter. The Commission notes that IEX will be required to submit separate filings under Section 19(b) of the Act and Rule 19b–4 to establish fees that it will charge to members and others persons using its facilities. Nevertheless, in its Second Response Letter, IEX noted that, as an exchange, it intended to charge a flat transaction fee. *See* IEX Second Response at 9.

[141] *See, e.g.,* Capital Group Letter; Southeastern Letter; Shatto First Letter; Navari First Letter; Oppenheimer Funds Letter; Healthy Markets Letter; Norges Bank Letter; Burgess Letter; fi360 Letter; TRS Letter. *But see* NYSE First Letter at 9 (arguing that IEX's proposed menu of order types is not necessarily "simple" and the potential different combinations of instructions for limit orders is in the hundreds).

[142] *See, e.g.,* T. Rowe Price Letter at 1–2; Navari Second Letter; Healthy Markets Letter at 2–4; Jefferies Letter at 3; Chen & Foley Letter at 2–3; Leuchtkafer Second Letter at 9; Budish Letter at 4. *See also* Burgess Letter; Capital Group Letter; Franklin Templeton Investments Letter; Schroeder M Letter; Leeson Letter; Lupinski Letter; Oorjitham

Among the commenters who were critical of aspects of IEX's proposal, most focused on issues surrounding the coil, the operation of and advantages that IEX initially proposed to be provided to IEX's affiliated outbound router, and IEX's proposed order types, which are discussed in detail below.[144] Some commenters suggested that retail orders would not receive better executions on IEX,[145] and that IEX has not used historical data or other methods to support its investor protection claims.[146] Other commenters did not express a view on whether the Commission should approve or disapprove IEX's application.[147]

2. Trading System Overview

IEX will operate a fully automated electronic order book, and will not maintain or operate a physical trading floor. Only broker-dealer members of IEX and entities that enter into market access arrangements with members (collectively, "Users") will have access to the IEX system.[148] Users will be able to electronically submit market orders, limit orders, and numerous other types of orders to the Exchange from remote locations. IEX will allow firms to register as market makers with affirmative and negative market making obligations, but will not require market makers to be registered before IEX lists or trades a security.[149] Non-marketable orders submitted to IEX could be displayed or non-displayed, depending on the instructions indicated by the IEX member submitting the order.[150] Displayed orders will be displayed on an anonymous basis at a specified price. The IEX system will continuously and automatically match orders pursuant to price/time priority, provided that displayed orders and displayed portions of orders will have priority over non-displayed orders and non-displayed portions of orders at the same price without regard to time.[151] For any portion of an order that does not execute on IEX, IEX will direct the unfilled portion to away markets for execution through IEX Services LLC ("IEXS"), IEX's wholly owned single-purpose outbound router, unless the terms of the order direct IEX not to route such order away.[152]

With respect to the price of executions that would occur on IEX, the IEX system is designed to comply with the order protection requirements of Rule 611 of Regulation NMS,[153] commonly referred to as the "Order Protection Rule," by requiring that, for any execution to occur on the IEX Exchange during regular trading hours, the price must be equal to, or better than, the "protected quotation," unless an exception to Rule 611 applies.[154] IEX also will protect the national protected best bid and offer during its pre-market and post-market sessions.[155] In addition, the Commission believes that IEX's rules address locked and crossed markets, as required by Rule 610(d) of Regulation NMS,[156] in that they reflect that IEX is designed not to disseminate interest that locks or crosses a protected quote, require Users to reasonably avoid displaying interest that locks or crosses any protected quotation, and are reasonably designed to assure the reconciliation of locked or crossed interest.[157]

3. Non-Displayed Order Types and Processing

Limit orders that a User marks as non-displayed will not be displayed to anyone and will be ranked in the IEX system at their specified price, subject to the "Midpoint Price Constraint," which is a price sliding process that prevents non-displayed limit orders from being ranked in the IEX system at a price that is more aggressive than the midpoint of the NBBO.[158] The Midpoint Price Constraint will prevent a non-displayed limit order on IEX's order book from resting at a price that locks or crosses the NBBO.

Due to IEX's Midpoint Price Constraint functionality, IEX has proposed a "Book Recheck" functionality that is activated in response to a change to the NBBO, the IEX order book, or when IEX receives inbound messages. When Book Recheck is activated, certain resting, non-displayed orders become "active"[159] and eligible to execute (as the remover of liquidity) against the updated contra-side in IEX's order book.[160] As a result of the Book Recheck functionality, these resting, non-displayed orders may

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Letter; Eric K Letter; Grey Letter; Spear Letter; Baggins Letter; Nixon Letter; Campbell Letter; Moses Letter; Huff Letter; Kaye Letter; Jean Letter; Gloy Letter; Givehchi Letter; Kara Letter; Hiester Letter; Benites Letter; Eustace Letter; Ramirez Letter; Luce Letter; Arnold Letter; Tidwell Letter; Doyle Letter; Long Letter; Kim Letter; Mannheim Letter; Oppenheimer Funds Letter; Israel Letter.

[143] *See* Angel Letter at 3–5. The pilot program suggested by this commenter would be to measure the effect on the market of protecting IEX's quotation notwithstanding the "speed bump." *See id.* at 4–5. According to the commenter, if the pilot caused material harm, it could be halted, in which case IEX could still operate as an exchange but without having its quotes protected under Regulation NMS. *See id.* at 5. *See also* Wolfe Letter at 3 (agreeing with the pilot approach suggested in the Angel Letter). IEX has not proposed such an approach and therefore such an approach is not before the Commission. *See* Exchange Act Section 19(a)(1).

[144] *See* NYSE First Letter; Nasdaq First Letter; BATS First Letter; Citadel First Letter; Citadel Second Letter; Citadel Third Letter; Hudson River Trading First Letter; Hudson River Trading Second Letter; FIA First Letter. In addition, one commenter opposed to approval of IEX's exchange application asserted that IEX has not provided any data establishing the negative aspects of speed-based trading that IEX's intentional delay is meant to counteract or any data that quantifies how its intentional delay would protect investors from such speed-based trading in a way that existing exchanges do not. *See* Modern Markets Initiative Letter. Another commenter opposed to IEX's application believed it is highly probable that the potential marginal savings in execution costs for the "limited population that use IEX would not exceed the wide increase in infrastructure costs for all market participants" as a result of further fragmentation of the market. *See* Loh Letter. *See* discussion, *infra* Section III.C., of IEX's proposed POP/coil delay, including the comments thereon.

[145] *See* Markit Second Letter at 4–6; AK Financial Engineering Consultants First Letter; Anonymous June 16 Letter.

[146] *See* Anonymous March 14 Letter at 1–2. *But see* Anonymous March 18 Letter (group of anonymous traders noting that they "have empirically found IEX orders to lower transactions costs" relative to other exchanges).

[147] *See, e.g.*, Virtu Letter; Healthy Markets Letter; Tabb Letter; Aesthetic Integration Letter.

[148] To obtain authorized access to the IEX System, each User must enter into a User Agreement with IEX. *See* IEX Rule 11.130(a).

[149] *See* IEX Rules 11.150 through 11.154. IEX's rules relating to market makers are similar to the rules of other national securities exchanges. *See, e.g.*, BATS Exchange Rules 11.5 through 11.8.

[150] *See* IEX Rule 11.220(a)(1).

[151] *See* IEX Rule 11.220(a)(1). The Commission notes that some commenters referenced a feature of the IEX ATS called "broker priority." *See* Citadel First Letter at 8; Birch Bay Letter at 1–2; Loh Letter. IEX has not included as part of its Form 1 application a "broker priority" feature and therefore that feature is not before the Commission as it considers IEX's Form 1 application.

[152] *See* IEX Rule 11.230(b). *See also* Amendment Nos. 2 and 3.

[153] 17 CFR 242.611.

[154] *See* IEX Rule 11.230(a)(2). *See also* 17 CFR 242.611 (defining "protected quotation").

[155] *See* IEX Rule 11.230(a)(2)(B).

[156] 17 CFR 242.610(d).

[157] *See* IEX Rule 11.310.

[158] *See* IEX Rule 11.190(h)(2). Specifically, a non-displayed order on IEX with a limit price more aggressive than the midpoint of the NBBO would be priced at the midpoint, and the price would automatically be adjusted in response to changes in the NBBO to be equal to the less aggressive of the order's limit price or the midpoint of the NBBO. *Id.*

[159] The term "active order" is defined by IEX to mean an order checking against the IEX order book for contra-side interest against which to execute, and includes new incoming orders, orders posting to the order book after having been routed to away trading centers, and orders re-checking the order book pursuant to IEX Rule 11.230(a)(4)(D).

[160] *See* IEX Rule 11.230(a)(4)(D).

execute against contra-side orders on the order book that were ineligible for execution, or did not satisfy the order's conditions (*i.e.,* minimum quantity), when they were originally booked. Through such executions, Book Recheck also may help alleviate internal locks that may occur on IEX's order book at the midpoint of the NBBO in certain scenarios involving contra-side, non-displayed, minimum quantity orders.

In addition, IEX proposed several pegged order types—primary peg, midpoint peg, and discretionary peg—all of which would be non-displayed with prices that are automatically adjusted by the IEX system in response to changes in the national best bid and offer ("NBBO") (subject to a limit price, if any).[161] As noted below, updates to these types of non-displayed pegged orders would be processed within the IEX trading system without being subject to the proposed coil delay.[162] Some commenters criticized IEX's proposed non-displayed order types, and in particular IEX's proposed handling of pegged orders.[163] Some of these commenters also specifically criticized IEX's proposed discretionary peg order type.[164]

IEX's proposed discretionary peg order type is a non-displayed, pegged order that, upon entry, is priced by the IEX system to be equal to the less aggressive of the midpoint of the NBBO or the order's limit price, if any. Any unexecuted portion of the order is posted non-displayed on the order book and ranked at the less aggressive of the near-side primary quote (*i.e.,* the NBB for buy orders, the NBO for sell orders) or the order's limit price, if any. The IEX system automatically adjusts the price and ranking of the order in response to changes in the NBB (NBO) for buy (sell) orders so that it remains pegged at the near-side primary quote, up (down) to the order's limit price, if any. Once posted to the IEX order book, a discretionary peg order can "exercise discretion" up to (for buy orders) or down to (for sell orders) the midpoint of the NBBO in order to meet the limit price of active orders on the order book, but only when the IEX system determines the near-side, primary quote to be "stable," *i.e.,* not in the process of moving down (up) in the case of buy (sell) orders. If the IEX system deems the near-side primary quote to be "unstable" (sometimes referred to as a "crumbling quote") and therefore in the process of moving down (up) in the case of buy (sell) orders, the discretionary peg order will not be permitted to exercise any discretion in order to meet the limit price of an active order, and will be executable only at its pegged price, *i.e.,* the near-side primary quote.

Quote "stability" or "instability" is an assessment that the IEX system makes in what IEX describes as real-time, based on a pre-determined, objective set of conditions that are detailed in IEX's proposed rule.[165] By not permitting resting discretionary peg orders to execute at a price that is more aggressive than the primary quote during periods of quote "instability," the IEX system is intended to attempt to protect resting discretionary peg orders from unfavorable executions when the market is moving against them. Once the market has moved and the IEX system deems the near-side primary quote to be "stable," discretionary peg orders are re-ranked at the new near-side primary quote, and permitted to exercise discretion up to (for buy orders) or down to (for sell orders) the midpoint of the NBBO in order to meet the limit price of active orders on the order book and thereby potentially provide price improvement to such active orders.

Certain commenters that criticized IEX's discretionary peg order assert that IEX's determination of quote stability and the resulting implications for resting discretionary peg orders amounts to IEX performing services that are typically performed by broker-dealers exercising discretion over customer orders.[166] Two of these commenters claim that allowing IEX to offer its discretionary peg functionality would be inconsistent with the Commission's prior disapproval of a Nasdaq proposal to establish "benchmark orders" and suggests that the Commission articulate when it is and is not appropriate for an exchange to offer services that have traditionally been performed by broker-dealers.[167] The other commenter contends that, due to what it refers to as "the doctrine of regulatory immunity," IEX would be shielded from liability for any errors it makes in determining quote stability whereas broker-dealers can be liable to their customers for order handling errors.[168] This commenter also asserts that IEX's discretionary peg order is overly complex and "would potentially open the door to a virtually infinite range of exchange predictive order types." [169]

With regard to its discretionary peg order, IEX states that any action taken with respect to such an order is based on system logic and entirely automated, like other pegged orders.[170] IEX also represents that its rules set forth "the precise mathematical formula" that IEX uses to determine whether a "crumbling quote" situation exists.[171] In addition, IEX notes that other exchanges offer non-displayed pegging and discretionary order types and asserts that IEX's discretionary peg order type does not raise any novel regulatory issues.[172] Further, IEX argues that the Commission's disapproval of Nasdaq's proposal to offer "benchmark orders" was based on Nasdaq's failure to adequately explain "how it would apply the controls required by Rule 15c3–5 under the Exchange Act to benchmark child orders" and the fact that "benchmark orders would not initially be directed to the Nasdaq matching engine, raising potential competitive concerns in relation to Nasdaq members." [173] IEX claims that the Commission's disapproval of Nasdaq's proposal "clearly differentiates the proposed Nasdaq functionality from IEX's Discretionary Peg order type" and that IEX's discretionary peg functionality "is entirely different than the Nasdaq proposal to offer benchmark order routing strategies." [174]

The Commission does not believe that its disapproval of the Nasdaq benchmark order proposal is apposite here. In contrast to IEX's proposed discretionary peg order, Nasdaq's proposed "benchmark orders" were not actually exchange orders that would have been executable by the Nasdaq matching engine upon entry. Rather, the initial parent order would have been directed to a third-party application that operated a suite of order execution algorithms (*i.e.*, Volume Weighted Average Price, Time Weighted Average Price, or Percent of Volume).[175] The algorithm thereafter would have attempted to replicate the selected benchmark by generating and routing child orders to the Nasdaq matching engine or other trading centers.[176] The Commission determined that there were inadequate assurances in Nasdaq's proposal as to how the child orders generated by the Nasdaq application would be subject to appropriate risk controls under the Market Access Rule, Rule 15c3–5 under the Act, and how Nasdaq's provision of such services would not impose an undue burden on competition.[177] In contrast, IEX's discretionary peg order is an order type that is received directly into the IEX book and executable by the matching engine upon entry, and thus the same issues of whether child orders generated by an exchange facility are subject to appropriate risk controls under the Market Access Rule or would result in the exchange imposing an undue burden on competition are not implicated by IEX's discretionary peg order type.

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[161] *See* IEX Rule 11.190(a)–(b).

[162] *See* note 206, *infra*, discussing how the proposed coil delay also does not apply to non-displayed limit orders subject to the Midpoint Price Constraint.

[163] *See, e.g.,* FIA First Letter at 4; FIA Second Letter at 2; Citadel First Letter at 7–10; Citadel Fifth Letter at 2–5; NYSE First Letter at 9–10; NYSE Third Letter at 4–7; Hudson River Trading First Letter at 2–7; Jones C Letter at 2–3; Nasdaq Third Letter at 2. These commenters argue that IEX's proposed handling of resting pegged orders—which, as detailed below, would occur without any delay from IEX's POP/coil—would incentivize dark liquidity over displayed liquidity on IEX. This argument is discussed in the section below that addresses the POP/coil.

[164] *See* NYSE First Letter at 10; NYSE Fourth Letter at 3–4; Citadel First Letter at 9–10; Citadel Fifth Letter at 5–7; Nasdaq Third Letter at 2–3.

[165] *See, e.g.,* IEX Rules 11.190(b)(10) (concerning the discretionary peg order type) and 11.190(g) (concerning quote stability). This functionality is also referred to as IEX's "crumbling quote" indicator.

[166] *See, e.g.,* NYSE First Letter at 10; NYSE Fourth Letter at 2–4; Citadel First Letter at 9–10; Citadel Fifth Letter at 5–7; Nasdaq Third Letter at 2–3.

[167] *See* NYSE First Letter at 10 (citing Securities Exchange Act Release No. 68629 (January 11, 2013), 78 FR 3928 (January 17, 2013) (SR–NASDAQ–2012–059) ("Benchmark Order Disapproval"); NYSE Fourth Letter at 3–4; Nasdaq Third Letter at 2–3.

[168] *See* Citadel First Letter at 9–10.

[169] Citadel Fifth Letter at 6–7.

[170] *See* IEX First Response at 17.

[171] *See* IEX Second Response at 18.

[172] *See* IEX First Response at 17.

[173] *See* IEX Second Response at 13.

[174] *See id.*

The Commission also notes that existing exchanges offer both discretion and pegging functionalities, including the combination of both of those features in a single order type.[178] Thus, an order type that offers both discretion and pegging features is not novel. Nevertheless, IEX's proposed discretionary peg order type is unique in the way that the discretion functionality will be turned "on" or "off" depending on IEX's quote stability determination. With respect to this feature, IEX Rule 11.190(g) delineates the specific conditions under which IEX discretionary peg orders will or will not be eligible for execution up (down) to the midpoint by setting forth the mathematical formula that IEX uses to determine quote stability.[179] IEX has thus encoded in its rule the totality of the discretionary feature of its proposed discretionary peg order type, which the Commission believes is a close variant on the discretion and pegging functionality that presently exists on other exchanges. Moreover, as a self-regulatory organization, IEX would be required to submit a proposed rule change to the Commission pursuant to Section 19(b) of the Act[180] prior to implementing any change to the proposed discretionary peg order type, including the quote stability formula. Thus, contrary to the assertions of commenters critical of IEX's proposed "discretionary" peg order type,[181] the Commission does not believe that the hardcoded conditionality of the IEX proposed "discretionary" peg order type provides IEX with actual discretion or the ability to exercise individualized judgment when executing an order. Rather, if IEX's fixed formula determines the quote to be stable, the discretionary peg order can execute up to the midpoint; if it does not deem the quote to be stable, then it will hold the order to its pegged price. As such, IEX would not exercise discretion over the routing and execution of a resting order.[182] The Commission reiterates that if, for any reason, IEX determines to alter or deviate from its quote stability formula set forth in its rule as it applies to determining quote stability when handling discretionary peg orders, IEX would need to file a proposed rule change with the Commission pursuant to Section 19(b) of the Act[183] prior to implementing any such change.

4. Order Type Transparency and Complexity, and Odd Lots

More generally, some commenters contend that IEX's order types are not adequately described in IEX's rulebook, or suggest that they are uniquely complex.[184] In addition, one commenter argued that IEX should be required to add additional detail to its rules, including adding examples and a justification of the statutory basis for their consistency with the Exchange Act.[185] In response, IEX asserts that it "provides the same basic order types that are offered by all markets, along with the standard modifiers that are sought by investors and their brokers."[186]

The Commission believes that IEX constructed its proposed order type rules in a manner that is reasonably designed to present sufficient and comprehensive information on the available options and possible combinations. While IEX is responsible for ensuring that its rules fully and accurately reflect its systems capabilities and operations, the Commission believes that IEX has structured many of its rules using a template-like approach that is designed to provide basic information about fundamental combinations and system functionality. In addition, the Commission does not believe that IEX's order type rules are uniquely complex in light of existing exchange order type offerings. Accordingly, the Commission believes that IEX's order type rules are consistent with the Act and, in particular, the Section 6(b)(5) requirement that an exchange's rules be designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanisms of a free and open market and a national market system, and protect investors and the public interest.[187]

In addition, one commenter noted that IEX proposes not to display odd-lot orders and suggests that the Commission should consider whether this would systematically disadvantage smaller orders that might be submitted by retail investors.[188] In response, IEX noted that current exchanges vary in how they handle odd-lots, and stated that IEX's approach "is designed to ensure that the IEX proprietary market data feed does not include information that cannot be reported to the SIPs."[189] IEX also contends that the commenter's conflation of the treatment of odd-lots with the treatment of retail investors is improper because "these do not necessarily go hand-in-hand."[190] The Commission is not aware of any evidence that the non-display of odd lot orders through proprietary market data feeds would systematically disadvantage retail investors. The Commission does not believe this approach would unfairly discriminate against any type of investor, as any investor may use odd-lot orders.

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[175] *See* Benchmark Order Disapproval, *supra* note 167, at 3928.

[176] *See id.*

[177] 17 CFR 240.15c3–5. *See also* Benchmark Order Disapproval, *supra* note 167.

[178] *See, e.g.*, Nasdaq Rule 4703(g).

[179] *See* IEX Rule 11.190(g). One commenter asserted that IEX's crumbling quote determination is novel but also fully transparent, as IEX's rules disclose the full equation for determining whether there is a crumbling quote. *See* Healthy Markets Letter at 5.

[180] 15 U.S.C. 78s(b).

[181] *See supra* note 166.

[182] Thus, the Commission believes that one commenter's concerns related to what it refers to as "the doctrine of regulatory immunity" (*see supra* note 168) does not present any novel issues. As discussed, the Commission does not believe that IEX's quote stability determination provides IEX with actual discretion or the ability to exercise individualized judgment when executing an order. IEX will have liability similar to other registered national securities exchanges with respect to its order types, including its "discretionary" peg order type. Further, in response to this commenter's additional concern that the discretionary peg order "would potentially open the door to a virtually infinite range of exchange predictive order types" (*see supra* note 169), the Commission notes that new exchange proposed order types are subject to the rule filing process of Section 19(b) of the Act and Rule 19b–4 and the standards in Exchange Act Section 6(b), among other provisions. *See also* Form 19b–4, General Instructions.

[183] 15 U.S.C. 78s(b).

[184] *See, e.g.*, NYSE First Letter at 9 (noting that certain of [IEX's] proposed order types, such as the discretionary pegged order, are even more complex than those of other exchanges" and that the "tally of potential different combinations of instructions for limit orders alone is in the hundreds"). *See also* Citadel First Letter at 8–9; Nasdaq First Letter at 1–2; Nasdaq Third Letter at 1–2. Other commenters suggested the opposite though, and applauded IEX for offering a limited number of order types, which they assert simplifies trading and reduces risks for investors. *See, e.g.*, Healthy Markets Letter at 4; Oppenheimer Letter at 2; Southeastern Letter at 1; Navari Letter at 1; Capital Group Letter at 2; fi360 Letter at 3.

[185] *See* Nasdaq First Letter at 1–2.

[186] *See* IEX Second Response at 8.

[187] *See* 15 U.S.C. 78f(b)(5).

[188] *See* Nasdaq First Letter at 4.

5. The POP and the Coil

IEX's Point-of-Presence ("POP") and "coil" infrastructure (collectively referred to as the "POP/coil delay") is how IEX Users will connect to IEX, and is one of the most widely commented upon features of IEX. As described in the Order Instituting Proceedings, several commenters expressed concern, among other things, that IEX's initially-published Form 1 lacked specific detail about how the POP/coil structure would work, including what messages and activity would—and would not—be subject to the delay.[191] IEX responded by supplementing the record through its first two response letters, and then amending its Form 1 in Amendment Nos. 2, 3, and 4.[192] IEX did include additional detail in proposed new rules as part of Amendment Nos. 2, 3, and 4 and the Commission published notice of those changes and solicited comment on them.[193] The POP/coil delay is material to the operation of IEX and so materially affects access of Users to the system that, as an exchange, IEX's rules must reflect with specificity the purpose, operation, and effect of the POP and coil. The Commission notes that IEX's two letters in response to comments provided the necessary detailed information on the POP and coil, and IEX's Amendment No. 2 contained, among other things, a proposed new rule to detail the POP and coil. The Commission believes that IEX has addressed the commenters' concern by adding a sufficiently detailed new rule to its rulebook to provide a description of the POP/coil structure. The Commission notes that commenters did not raise further concerns on this issue after publication of Amendment No. 2.

Access to IEX by all Users will be obtained through a POP,[194] which IEX represents is located in Secaucus, New Jersey.[195] According to IEX, after entering through the POP, a User's electronic message sent to the IEX trading system must physically traverse the IEX "coil," which is a box of compactly coiled optical fiber cable equivalent to a prescribed physical distance of 61,625 meters (approximately 38 miles).[196] After exiting the coil, the User's message travels an additional physical distance to the IEX trading system, located in Weehawken, New Jersey.[197] According to IEX, when the length of coil is combined with the physical distance from the POP to the IEX trading system in Weehawken, it equates to an equivalent 350 microseconds of latency.[198] All *incoming* messages (*e.g.,* orders to buy or sell and any modification to a previously sent open order) from any User would traverse the coil from the POP in order to initially reach IEX.[199] In addition, all *outbound* messages from IEX back to a User (*e.g.,* confirmations of an execution that occurred on IEX) would pass through the same route in reverse.[200] IEX's direct proprietary market data feed, which is an optional data feed that IEX would make available to subscribers, also would traverse the coil before being accessible to Users at the POP.[201]

Further, under IEX's Form 1 as amended, there is one type of inbound message and one type of outbound message that would *not* traverse the POP/coil, specifically:

1. Inbound proprietary market data feeds from other trading centers as well as the SIP feed to the IEX system would *not* traverse the POP/coil; and
2. Outbound transaction and quote messages sent from IEX to the applicable securities information processor ("SIP") would *not* pass through the POP/coil, but instead would be sent directly from the IEX system to the SIP processor for inclusion in the public consolidated market data feeds on the same basis as any other exchange.[202]

In addition, updates to resting pegged orders on IEX would be processed within the IEX trading system and would not require that separate messages be transmitted from outside the trading system, which would otherwise traverse the POP/coil, for each update.[203] The effect of this, in connection with the fact that orders sent inbound to IEX must traverse the POP/coil while IEX's matching engine will take in direct market data feeds from other trading centers without any POP/coil delay,[204] is that IEX intentionally employs a methodology using physical path latency to affect how long it takes for a packet of information to travel from the User to its matching engine but does not delay the IEX system's ability to detect and react to price changes at other trading centers.[205]

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[189] *See* IEX Second Response at 13.

[190] *See id.* (noting that "one study found that '20–25% of trades initiated by HFTs are odd lots, and that trades initiated by HFTs are more likely to be odd lots than trades initiated by non-HFTs.' ")

[191] *See, e.g.,* NYSE First Letter; Nasdaq First Letter; Citadel First Letter at 10–11; Citadel Second Letter at 2–3; BATS First Letter at 2; Weldon Letter. IEX noted that the POP/coil is described in its Form ATS, which has been published on IEX's Web site since it commenced operations as an ATS in October 2013, and has been "widely chronicled" across numerous publications. *See* IEX Second Response at 17–18.

[192] *See* IEX First Response; IEX Second Response; Amendment Nos. 2, 3 and 4. Under IEX Rule 11.510, the IEX routing logic would be able to access the IEX book via an access delay that imposes 350 microseconds of latency, identical to the POP/coil delay experienced by non-affiliated IEX users when they submit a non-routable order to the IEX book.

[193] *See* Order Instituting Proceedings, *supra* note 13.

[194] *See* IEX Rule 11.510; *see also* Amendment Nos. 2 and 3.

[195] *See* IEX First Response at 3.

[196] *See* IEX First Response at 3. The Commission notes, by way of analogy, that this is equivalent to a trading center locating its matching engine a certain distance (equivalent to the distance traversed during the POP/coil delay) from its nearest user or, alternatively, not permitting any user to be located closer than that distance to the matching engine.

[197] *See* Exhibit E to IEX's Form 1 submission, at 12. *See also* IEX First Response at 3.

[198] *See* IEX Rule 11.510 ("Communications with the System from the POP are subject to an equivalent 350 microseconds of latency between the network access point of the POP and the System at the primary data center (due to traversing the physical distance provided by coiled optical fiber and geographic distribution)"); *see also* IEX First Response at 3. A microsecond is one millionth of a second.

[199] *See id.*

[200] *See id.* As a result, a non-routable immediate-or-cancel ("IOC") order, which is a type of order that IEX would permit Users to send to the IEX system, would traverse the proposed POP/coil (and its attendant 350 microsecond delay) before arriving at the IEX system and potentially executing against a displayed quotation on IEX. Likewise, the response from the IEX system to the User indicating the action taken by the IEX system with respect to such IOC order also would traverse the POP/coil and experience a 350 microsecond delay. *See id.* The POP/coil delay's consistency with the Act is discussed further below in this section. *See also* Final Interpretation, *supra* note 13.

[201] *See* IEX Rule 11.510; *see also* IEX First Response at 3.

[202] *See* IEX Rule 11.510(c)(2); *see also* IEX First Response at 4. As explained in the Order Instituting Proceedings, under IEX's Form 1 as it existed prior to Amendment No. 2, orders routed outbound from IEX through IEXS to away trading centers for execution (as well as reports back to IEX from those away trading centers) also would *not* have traversed the POP/coil (though execution and transaction reports sent from IEX back to Users *would* traverse the POP/coil and thus would be delayed). This is because IEX would have initially directed the entirety of all orders, including routable orders, to the IEX matching engine and then routed away any excess shares via IEXS directly (and without having to first pass through the POP/coil delay as it routes shares outbound). In Amendment Nos. 2, 3, and 4, IEX proposed to re-design the way the IEX system would handle routable orders, as described below, in order to place its outbound routing function on parity with competing broker-dealers.

[203] *See* IEX Rule 11.510(c)(1) (noting that order book processing occurs within the IEX system and does not traverse the POP); *see also* IEX First Response at 3–4.

[204] *See* IEX Rule 11.510; *see also* IEX First Response at 4.

Accordingly, IEX imposes an intentional delay on Users' ability to access IEX's matching engine but the delay does not apply to IEX's adjustment of resting pegged order prices on its book.[206] This provides IEX's matching engine with a time advantage[207] to allow it to more effectively manage the price update process for non-displayed pegged orders resting on its book when the market moves. However, as a by-product of delaying access to non-displayed pegged orders on its book, IEX necessarily delays access to all other interest on its book, including its displayed quotation.

In other words, the purpose of IEX's coil is to provide an intentional buffer that slows down incoming orders to allow IEX's matching engine to update the prices of resting "pegged" orders when away prices change to protect resting pegged orders from the possibility of adverse selection when the market moves to a new midpoint price.[208] The allowable price of a "pegged" order will change whenever the best displayed price across all exchanges changes, but it takes time for IEX's system to receive other exchange data feeds and recalculate the price of each pegged order resting on its book. For various reasons, IEX's systems may not recalculate prices as fast as some of the fastest low-latency traders in the market are able to send orders accessing pegged orders resting on IEX at potentially "stale" prices. The Commission believes that the application of the POP/coil delay delays the ability of low-latency market participants to take a "stale"-priced resting pegged order on IEX (*i.e.,* before IEX finishes its process of re-pricing the pegged order in response to changes in the NBBO) based on those market participants' ability to more effectively digest direct market data feeds and swiftly submit an order before IEX finishes its process of updating the prices of pegged orders resting on its book. According to IEX, this setup is designed to "ensure that no market participants can take action on IEX in reaction to changes in market prices before IEX is aware of the same price changes on behalf of all IEX members."[209]

Aside from whether the POP/coil delay affects IEX's ability to have an "automated" and thus "protected" quotation under Regulation NMS, discussed below,[210] the Commission has considered whether it is consistent with the Act and the rules thereunder, in particular Section 6 of the Act. Among other things, Section 6 requires that an exchange's rules be designed to protect investors and the public interest, not be designed to permit unfair discrimination among brokers, dealers, or customers, and not impose any unnecessary or inappropriate burden on competition. For IEX's POP/coil delay, discussed below, the Commission finds that IEX's proposed rules are designed to operate in a manner that is consistent with the Act in that they are designed to protect investors and the public interest, are not designed to permit unfair discrimination, and would not impose any unnecessary or inappropriate burden on competition.

The Commission first considers IEX's POP/coil delay as applied to outbound data. The POP/coil delay applies to IEX's outbound proprietary market data, other than the data it sends to the SIP. Doing so allows market participants to execute on IEX while slightly delaying the news of that execution to IEX's proprietary market data feed and to the participants to the trade (through not to the applicable SIP), which in effect allows the order sender to avoid the potential for information leakage when subsequently accessing liquidity on other markets before news of its execution on IEX could affect resting liquidity on those markets (*e.g.,* potentially resulting in cancellations or re-pricing of interest resting on away markets). Exchanges are not required to offer proprietary market data, but those that do must offer it to all market participants in a not unfairly discriminatory manner.[211] Because IEX delays its proprietary market data feed uniformly to all IEX users, as well as to its routing logic, the Commission believes that the outbound delay of IEX market data is not unfairly discriminatory.

The Commission similarly concludes that IEX's inbound POP/coil delay is not unfairly discriminatory and does not impose an unnecessary or inappropriate burden on competition. The delay imposed on inbound messages benefits resting pegged orders on IEX because that delay, together with the fact that IEX takes in direct data feeds from other exchanges unencumbered by the delay, allows IEX to update the prices of resting pegged orders in response to changes in the NBBO (which may include displayed orders on IEX) as quickly as IEX is able to receive data and calculate it before incoming messages, including incoming orders seeking to execute against pegged orders, reach the matching engine. At the same time, the POP/coil delay appears to provide no protection or benefits for displayed orders or non-displayed orders at fixed limit prices.[212] Several commenters critiqued this aspect of IEX's design as treating resting pegged orders preferentially, which they assert will incentivize dark liquidity on IEX (in the form of pegged orders in particular) over displayed liquidity.[213] Most of these commenters suggested that this is contrary to the central purpose of an exchange to provide price discovery through displayed liquidity, and that price discovery, and overall market quality, will deteriorate as a result.[214] Commenters on the Notice of Interpretation also criticized what they termed IEX's "selective" application of its POP/coil delay. One such commenter opined that geographic delays are "inescapable" but "do, in fact, complicate the markets in the presence of Reg NMS" and argued that the proposed interpretation should not apply to "intentional delays that are selective and therefore not equivalent to geographic latencies." [215] Another commenter criticized a potential access delay that would "treat dark orders more favorably than displayed orders," which it characterized as a "significant departure from the way current exchanges operate" and "would lead to less transparent markets, wider spreads and higher costs for investors." [216] These commenters' concern with the "selective" application of an access delay is not so much that an intentional delay is necessarily inconsistent with Rule 611, but that an exchange might impose the delay on others but not itself, thereby advantaging certain types of orders (*i.e.*, pegged orders) or market participants over others.[217]

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[205] *See* IEX Rule 11.410 (detailing the direct feeds that IEX uses as the primary source of market data that it uses to inform its matching engine's view of the consolidated best prices in the marketplace).

[206] In addition, the POP/coil delay does not apply to the operation of IEX's Midpoint Price Constraint, discussed above, which affects resting non-displayed limit orders with limit prices that are more aggressive than the midpoint of the NBBO. *See* IEX Rule 11.190(h)(2). References herein to "pegged" orders for purposes of discussing IEX's adjustment of resting order prices with no access delay includes non-displayed limit orders subject to the operation of the Midpoint Price Constraint, which are effectively pegged by IEX to the NBBO midpoint, subject to the order's limit price.

[207] *See* IEX Second Response at 2.

[208] However, as a byproduct of delaying access to non-displayed pegged orders on its book, IEX necessarily delays access to all other interest on its book, including its displayed quotation.

[209] *See* IEX First Response at 4.

[210] *See infra* Section III.C.7., Protected Quote Status, for a discussion of the status of IEX's quotation under Regulation NMS.

[211] *See* 15 U.S.C. 78f(b)(5).

[212] *See, e.g.,* Budish Letter at 2, 4–5 (noting that IEX's POP/coil structure would prevent latency arbitrage of non-displayed pegged orders on IEX but would not prevent latency arbitrage of standard displayed limit orders). The POP/coil, because it will delay all inbound message traffic from all members equally, will not provide any advantages for displayed and non-pegged orders. For example, if a displayed limit order to sell is resting on IEX at $10, and away markets all move to a higher price of $10.01 to sell, the User resting at IEX may also want to adjust the price of its order to track the market. However, pursuant to its rules, IEX cannot unilaterally adjust the price of a non-pegged limit order resting on its book at $10; rather, the User needs to send a message to IEX with instructions on what to do. As it is doing that, a low-latency trader may be able to send in an order to buy against that $10 offer to sell, and may be able to reach the POP before the member that posted that order is able to send in a cancellation and replace it with an order to sell at $10.01. Since the low-latency trader's message to buy and the member's cancel message both must enter through the POP and traverse the coil, the race simply takes place at the POP and therefore the two market participants are in the same position on IEX as they would be on other markets without intentional access delays.

[213] *See* FIA First Letter at 4; FIA Second Letter at 2; Citadel First Letter at 7–10; Citadel Fifth Letter at 2–5; NYSE First Letter at 9–10; NYSE Third Letter at 4–7; Hudson River Trading First Letter at 2–7; Hudson River Trading Second Letter at 2–4; Jones C Letter at 2–3; Nasdaq Third Letter at 2.

Other commenters believed that IEX's proposed re-pricing of resting pegged orders without any POP/coil delay would not be problematic.[218] One commenter found no material distinction between pegged orders on IEX not being subject to the POP/coil delay and how existing exchanges reprice resting pegged orders, noting that existing exchanges reprice resting pegged orders without being subject to "non-trivial" latency associated with transiting the exchanges' order entry gateways.[219]

In response, IEX represented that it will provide a "powerful incentive" for Users to submit displayed orders because displayed orders will have priority over non-displayed orders at the same price.[220] IEX also noted that it seeks to "bring the benefits of exchange oversight and regulation to more of the trading that currently happens off-exchange." [221]

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[214] *See* NYSE First Letter at 9–10 (stating that IEX would be unique "in that all pegged orders would be dark and pegged orders would be provided advantages that other orders on IEX would not enjoy" and that the POP/coil and Book Recheck combine to favor pegged orders to such an extent that "it is likely that IEX's order book would be composed primarily, or entirely, of these dark, pegged orders and would not be performing one of the central functions of a registered exchange, which is to foster the price discovery process through the display of orders"); NYSE Third Letter at 4, 7; Citadel First Letter at 8 (suggesting that "IEX's real aim is to create a dark pool on a lit venue to provide itself with regulatory immunity and other benefits afforded to national securities exchanges"); Hudson River Trading First Letter at 2–7 (expressing concern that IEX's POP would harm price discovery because it offers no protection to displayed limit orders, which "provide the foundation for price discovery," but delays incoming limit orders and outgoing market data for the benefit of non-transparent pegged orders); Hudson River Trading Second Letter at 4; Jones C Letter at 2–3 (arguing that "IEX is effectively using the discriminatory delay to tilt the playing field, artificially attracting pegged orders from other venues" which will "force other exchanges to introduce similar disparities to avoid losing pegged orders to IEX" and "which will result in more dark liquidity and less timely price discovery market-wide"). One such commenter offered an analysis that attempted to quantify the purported economic advantages and disadvantages implicated by IEX's proposed handling of resting pegged orders (including the cost to market participants routing orders to IEX when resting pegged orders on IEX, due to the access delay, "fade" to worse prices before they can be accessed), while also noting the limitations of his analysis (including that "[i]n reality, market participants may change their order submission behavior to substantially blunt IEX's pegged order repricing scheme" by adjusting for the latency imposed by the POP/coil delay when routing to IEX). *See* Jones C Letter at 3–5. Other commenters criticized that commenter's analysis. *See* Themis Third Letter; Hovanec Seventh Letter. In particular, one of these commenters rebutted the analysis as "just measuring transient effects on an NBBO after a trade and then attributing all of that fade as a 'disadvantage' of the speed bump, which he puts at $400 million annually just for Nasdaq activity." *See* Themis Third Letter at 2.

Another commenter recommended that IEX be approved as a "manual" market without a protected quote, unless it developed and offered a "bypass" order type that "that foregoes potential price improvement associated with interacting with hidden mid-point peg orders to by-pass the delay and interact with protected quotes." *See* Hudson River Trading Second Letter at 4. The Commission notes that midpoint pegged orders, by definition, would be priced more aggressively than IEX's displayed quotation, and thus by foregoing execution against such midpoint pegged orders in order to execute against less aggressively priced displayed quotations, the suggested "bypass" order type would appear to violate the price priority of the resting midpoint pegged orders. In addition, if such an order type were able to execute against resting non-displayed primary pegged interest on IEX, the resting primary peg order would be subject to latency arbitrage as a result of the incoming order bypassing the POP/coil delay. The Commission further notes that the issue of permissible delays in accessing protection quotations is addressed in the Commission's Interpretation Regarding Automated Quotations Under Regulation NMS, which provides that, in the context of determining whether a trading center maintains an "automated quotation" for purposes of Rule 611 of Regulation NMS, the term "immediate" used in Rule 600(b)(3) does not by itself prohibit a trading center from implementing an intentional access delay that is *de minimis—i.e.*, a delay so short as to not frustrate the purposes of Rule 611 by impairing fair and efficient access to an exchange's quotations. *See* Final Interpretation, *supra* note 13.

[215] FIA PTG Comment Letter on Notice of Proposed Interpretation ("Interp Letter") at 6. The commenter criticized the proposed interpretation for not distinguishing "between geographic delays, which apply equally to all information communicated between remote locations, and selective delays like those proposed by IEX" and argued that such delays, "even very short ones, open the door for behaviors that are fundamentally inconsistent with Reg NMS" and "would make Reg NMS requirements around order protection and locked and crossed markets essentially unworkable." *Id.* at 2–3. Another commenter argued that an intentional delay can impair a market participant's ability to access a protected quotation as it could create an "un-level playing field" when "an exchange could update certain orders before allowing members to update theirs." *See* MMI Interp Letter at 1. The commenter noted that an investor selling to a resting pegged order that IEX updates while the customer is traversing the POP/coil delay would end up selling to the pegged order at a worse price than she would have sold at had IEX not been able to reprice the pegged order outside of the POP/coil delay. *See* MMI Interp Letter at 2. In other words, according to that commenter, IEX's POP/coil delay only protects certain investors (those with dark peg orders resting on IEX) and may harm other long-term investors who cannot compete "against the exchange's superior speed." *See* MMI Interp Letter at 2. The commenter also argued that selective access delays may interfere with a broker's best execution obligation, and may distort order execution and routing. *See* MMI Interp Letter at 2–3. Another commenter opposed "non-symmetrical" delays and argued that they add complexity and reduce the likelihood of capturing visible liquidity in the equities markets, which can impact liquidity in the options markets. *See* Weldon Interp Letter at 1–2. While true that IEX's POP/coil delay benefits resting non-displayed orders, investors routing to displayed liquidity on IEX will not "compete" against IEX in the sense of racing to access a resting order before IEX can reprice it—because IEX will not reprice displayed orders, there is no such race. Further, the Commission does not believe that such a delay will interfere with best execution or distort routing so long as it is *de minimis—i.e.*, a delay so short as to not frustrate the purposes of Rule 611 by impairing fair and efficient access to an exchange's protected quotations.

[216] *See* NYSE Interp Letter at 4 (arguing that IEX's "preferential treatment of resting dark orders" is novel because "[w]hile other markets update pegged orders in the same way as IEX, they do not intentionally delay the ability to update displayed orders on their book or to enter or cancel interest"). *See also* Citadel Interp Letter at 8. One commenter opined that allowing an exchange to re-price displayed orders during and outside of an access delay "would render such orders conditional" and "result in precisely the kind of 'maybe' quotations Rule 611 was designed to prevent." Markit Interp Letter at 2–3. The commenter urged the Commission to explicitly preclude exchanges from "utilizing the delay to re-price displayed orders." *Id.* at 2. The Commission notes that IEX will only reprice pegged orders, which are non-displayed. Non-displayed orders are not reflected in an exchange's quotations, and Rule 611 applies order protection to publicly displayed quotes only. Accordingly, an access delay that does not allow the repricing of displayed orders does not impact an exchange's displayed quotation, and cannot be said to lead to "maybe" quotations.

[217] *See, e.g.*, Citadel Interp Letter at 10 (recommending that intentional delays should "only be permissible where the intentional delay applies equally to all market participants and order types" where "no order type, such as pegged orders, would be permitted to circumvent access delays directly or indirectly by repricing without delay").

[218] *See* Markit Second Letter at 3; Healthy Markets Letter at 4–5. *See also* Trirogoff Letter (critiquing other commenters' arguments likening IEX's pegged order functionality to "last look" functionality).

[219] *See* Healthy Markets Letter at 4–5.

[220] *See id.*; *see also* IEX First Response at 17. The Commission notes that IEX represents that it intends to propose discount pricing for displayed orders. Any such proposal will be subject to the rule filing requirements of Section 19 of the Act and Rule 19b–4 thereunder.

[221] *See* IEX Second Response at 12–13. IEX noted that as an ATS, 8.76% of IEX matched volume

The Commission does not believe that the advantage IEX provides to pegged orders is unfairly discriminatory or imposes an unnecessary or inappropriate burden on competition. Rather, it is designed to ensure that pegged orders on IEX operate as designed and as reflected in IEX's rules by accurately tracking the NBBO, and that users of pegged orders on IEX can better achieve their goals when their pegged orders operate efficiently. To accomplish this, IEX slows down incoming order messages by 350 microseconds to allow it to update resting pegged orders when the NBBO changes, so that the resting pegged orders are accurately pegged to current market prices. Without this protection, pegged orders resting on IEX have the potential to be subject to "latency arbitrage" by those market participants using very sophisticated latency-sensitive technology, who can rapidly aggregate market data feeds and react faster than IEX to NBBO updates. In such case, pegged orders on IEX could be executed at disadvantageous "stale" prices that have not been updated to reflect the new NBBO. Further, because non-displayed pegged order types will be available to all Users of IEX, all Users will be able to benefit from this order type on IEX and thus utilize the POP/coil delay.

IEX's proposed POP/coil delay is thus narrowly designed to allow IEX to update the prices of non-displayed resting pegged orders so that they can achieve their intended purpose—pricing that is accurately benchmarked to the NBBO. Though the POP/coil delay does not benefit displayed limit orders or non-pegged non-displayed limit orders, such orders would not benefit from the symmetrical POP/coil delay because their purpose is to post or execute consistent with their fixed limit price. The Commission thus finds that IEX's ability to update the prices of resting pegged orders during the POP/coil delay is not designed to unfairly discriminate among members to the detriment of investors or the public interest and is intended to benefit investors that post pegged orders.

The Commission is engaged in an ongoing broad-based review of equity market structure, including whether there are appropriate incentives to display trading interest and whether the level of undisplayed liquidity may be impairing price discovery.[222] Through its POP/coil delay, IEX is seeking to address what it views as the detrimental effects of speed on pegged orders, and the Act does not foreclose reasonable and not unfairly discriminatory innovations that are designed to protect investors who seek to reliably place passive, non-displayed pegged orders on an exchange.

Finally, the Commission notes that the POP/coil delay applies to all IEX Users equally, and may not be bypassed, for a fee or otherwise.[223] Accordingly, the Commission concludes that IEX's proposed POP/coil delay is designed to protect investors and the public interest in a manner that is not unfairly discriminatory and that does not impose an unnecessary or inappropriate burden on competition.

6. Outbound Routing through IEXS

As noted above, IEXS, IEX's affiliated single-purpose outbound routing broker-dealer, will provide outbound routing services for IEX. As detailed in the Order Instituting Proceedings, under the initially published version of IEX's Form 1 (prior to Amendment No. 2), orders routed from IEX through IEXS to away trading centers for execution (as well as reports back to IEX from those away trading centers) would not have traversed the POP/coil (though reports communicated from IEX back to members would have traversed the coil). Several commenters expressed concern that this design would provide an unfair competitive advantage to IEXS over other routing brokers to most quickly and efficiently route to away markets,[224] and might lead other exchanges to implement similar features that would add complexity to the markets and be detrimental to market structure.[225] Some commenters recommended that orders sent from IEX to IEXS be subject to the same POP/coil delay as unaffiliated members.[226] Other commenters supported IEX's initially proposed routing structure.[227]

In response to these comments, IEX submitted Amendment Nos. 2, 3, and 4 to propose a complete redesign of the way its trading system will handle outbound routing by bifurcating its handling of non-routable and routable orders once they initially exit the coil and reach IEX.[228] Specifically, IEX will

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resulted from displayed orders and it expects that number to "increase substantially" if IEX becomes a registered exchange. *See id.* at 12.

[222] *See* Securities Exchange Act Release No. 61358 (January 14, 2010), 75 FR 3594 (January 21, 2010) (Concept Release on Equity Market Structure). While the Commission believes that IEX's application for exchange registration is consistent with the Act, the Commission notes that IEX's representation to propose and adopt additional incentives for placing resting displayed orders on IEX may further address commenters concerns, including execution priority for displayed orders at the same price as non-displayed orders (including pegged orders) and material pricing incentives to displayed orders. The Commission also notes that IEX would allow for registered market makers, who, if appointed, would need to maintain displayed quotes pursuant to IEX rules. *See* IEX Rule 11.150 (Registration as a Market Maker) and Rule 11.151 (Market Maker Obligations). In addition, the Commission observes that non-displayed order types, including pegged order types that are non-displayed, exist across exchanges today. *See, e.g.,* BATS BZX Rule 11.9(c)(9) (mid-point peg order). While one commenter asserts that the repricing of pegged orders in response to market movements is "a traditional broker-dealer service" (*see* Citadel Fifth Letter at 5), the Commission notes that many exchanges offer pegged orders that are repriced in a substantively identical manner. *See, e.g.,* BATS BZX Rule 11.19(c)(8) (pegged order); Nasdaq Rule 4703(d) (pegging). Lastly, while one commenter asserts that IEX is unique in that all of its pegged order types would be non-displayed (*see* NYSE First Letter at 9), the Commission does not believe that the design of IEX's proposed pegged order types is inconsistent with the Act for the reasons discussed in this order.

[223] A few commenters suggested that a 2012 proposed rule change from NASDAQ PHLX ("Phlx") should preclude IEX's quotations from being protected. *See* Securities Exchange Act Release No. 67680 (August 17, 2012), 77 FR 51073 (August 23, 2012) (SR–Phlx–2012–106) ("Phlx 5 Millisecond Proposal"). *See also* Nasdaq First Letter at 2–3; NYSE First Letter at 7 n.14; FIA First Letter at 2–3; Citadel First Letter at 4. In that matter, Phlx proposed instituting a five millisecond delay in the time between the receipt of an order and the time when it would be presented for execution against the PSX order book. *See* Nasdaq First Letter at 2. In response, IEX noted that while this delay would have applied to inbound liquidity taking orders, no such delay would have applied to liquidity adding orders. *See* IEX First Response at 8; IEX Second Response at 5. The Commission notes that Phlx ultimately withdrew its proposal, and therefore the Commission has not ruled on the merits of the Phlx proposal or its consistency with the Act. Nevertheless, the Commission notes that the structure and implementation of the delay proposed in the Phlx proposal appears to differ in significant respects from IEX's POP/coil, particularly with respect to its differential application to members depending on whether they were providing or taking liquidity.

[224] *See* BATS First Letter at 4–5; BATS Second Letter at 3–6; BATS Third Letter at 3; NYSE First Letter at 3–5; NYSE Second Letter at 3; Citadel First Letter at 6–7; Citadel Second Letter at 5–6; Citadel Third Letter at 1–2; FIA First Letter at 4–5; Tabb Letter at 2–3; Hudson River Trading First Letter at 3–7; Hudson River Trading Second Letter at 4–5; Markit First Letter at 1–3; Markit Second Letter at 3–4 and 6; Weldon First Letter.

[225] *See* Hudson River Trading First Letter at 6–7; BATS Second Letter at 4–5; Citadel Third Letter at 2; Hunsacker Letter; Weldon First Letter.

[226] *See* Markit First Letter at 3; BATS Second Letter at 5–6; Citadel First Letter at 6; Citadel Third Letter at 2; FIA First Letter at 5; Hunsacker Letter. IEX stated that, under its initially proposed approach to outbound routing through IEXS, IEXS would not receive market data from IEX (or any other market) or have any greater access to information than other IEX members. *See* IEX First Response at 14; *see also* IEX Second Response at 14. One commenter challenged IEX's claim and argued that IEX's purported argument concealed the fact that IEXS's competitive advantage does not involve or require IEXS receiving market data from IEX's own book. *See* Markit First Letter at 2.

[227] *See* Norges Bank Letter; Mannheim Letter; Sethi Letter.

[228] *See* IEX Sixth Response, at 1. The proposed revisions to accommodate the new routing process

Continued

direct non-routable orders to the IEX matching engine, while it will direct routable orders to the IEX routing logic.[229] According to IEX, the coil, when combined with the physical distance between the POP and the IEX trading system (herein referred to as the "POP/coil"), provides IEX Users sending non-routable orders with 350 microseconds [230] of one-way latency to the IEX book (hereinafter the "POP/coil delay").[231] For routable orders, however, IEX explains that it would insert an *additional* POP/coil delay within the IEX system to delay routable orders' access to the IEX book from the IEX routing logic (for those routable orders that the IEX routing logic determines to send to the IEX book) by an additional 350 microseconds (for a total delay of 700 microseconds before any portion of the routable order first reaches the IEX book).[232] Likewise, messages from the IEX order book back to IEX's routing logic also would be subject to this POP/coil delay in order to effect a latency for its routing logic that is identical to the latency experienced by IEX's non-affiliated members when receiving messages back from the IEX order book.[233] In addition, the routing logic would receive IEX exchange data products subject to the POP/coil delay.[234] IEX represents that the extra POP/coil delay between the routing logic and the IEX book is intended to place IEX in the same position as a third-party routing broker in reaching IEX's book through a POP/coil delay, such that IEX's ability to submit a routable order to its own order book would be identical to any other routing broker-dealer's ability to submit a routable order to the IEX order book despite the fact that the orders would traverse different paths in the system.[235] As such, IEX represents that its routing functionality would have no information advantage (*i.e.*, no special view of IEX's book, including displayed or non-displayed interest), and IEX represents that the proposal places its outbound routing functionality in an identical position to third-party routing broker-dealers when sending orders into the IEX matching engine and when receiving transaction information from the IEX matching engine.[236]

Given the additional POP/coil delay, Users submitting *routable* orders to IEX and Users submitting *non-routable* orders to IEX would not be subject to the same *cumulative* POP/coil delay. Non-routable orders would remain subject to the 350 microsecond delay into and out of the IEX matching engine via the initial POP/coil. Routable orders, however, would be sent to IEX's system routing logic first, and, if routed to IEX, would traverse a *new* POP/coil delay (with an additional 350 microsecond delay) when interacting with the IEX matching engine.[237]

In the Order Instituting Proceedings, the Commission noted that it was particularly interested in commenters' views as to whether the changes to IEX's outbound routing process set forth in IEX's Form 1, as amended by Amendment Nos. 2, 3 and 4, are consistent with the Act, in light of commenters' concerns that, under IEX's Form 1 prior to Amendment No. 2, IEX's proposed routing functionality and IEXS would have an advantage over other routing broker-dealers that would be unfairly discriminatory and an inappropriate burden on competition. Several commenters stated the changes to IEX's proposed routing functionality have sufficiently addressed these concerns and eliminated the advantage IEXS would have had over other routing broker-dealers under the original proposal.[238] One of these commenters questioned how the differing treatment of routable versus non-routable orders under IEX's amended proposal would be consistent with the Act, and in particular, how it would not be unfairly discriminatory or an inappropriate burden on competition.[239] Another commenter questioned whether the revised routing functionality would operate as effectively as the original proposal, and suggested IEX further clarify how its redesigned functionality would achieve its investor protection goals in comparison to the initial proposal.[240]

The Commission notes that it carefully scrutinizes exchange-affiliated routing brokers, and has scrutinized with particularity IEX's proposed operation of IEXS, both as initially proposed and as amended by Amendment Nos. 2, 3, and 4.[241] As noted in the Order Instituting Proceedings, the Commission previously has stated that an exchange-affiliated outbound router, as a "facility" of the exchange, will be subject to the exchange's and the Commission's regulatory oversight, and that the exchange will be responsible for ensuring that the affiliated outbound routing function is operated consistent with Section 6 of the Act and the

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are primarily addressed in IEX Rule 11.510 (Connectivity), as well as in IEX Rules 2.220 (IEX Services LLC as Outbound Router), 11.130 (Access), 11.230(b)–(c) (Order Execution), 11.240 (Trade Execution, Reporting, and Dissemination of Quotations), 11.330 (Data Products), and 11.410 (Use of Market Data Feeds and Calculations of Necessary Price Reference Points). IEX also proposed other changes in Amendment Nos. 2 and 3, including changes to proposed Rule 2.160 (Restrictions on Membership) to reflect the Series 57 exam; proposed new Rule 2.250 (Mandatory Participation in Testing of Backup Systems); proposed new Rule 9.217 (Expedited Client Suspension Proceeding); proposed new Rule 10.270 (Disruptive Quoting and Trading Activity Prohibited); changes to proposed Rule 11.190(a)(3) (Pegged Orders), (b)(8)–(10) (concerning pegged orders), and (g) (concerning quote stability for Discretionary Peg Orders); and changes to proposed Rule 11.260 (LIMITATION OF LIABILITY).

[229] *See* IEX Rule 11.230 (stating that an incoming non-routable order will attempt to be matched for execution in the IEX order book, and that, upon receipt of a routable order, the IEX system will process it in accordance with one of the available routing options, which may include routing IOC or FOK orders to the IEX order book). *See also* IEX Sixth Response at 1; Amendment Nos. 2 and 3; IEX Rule 2.220(a) (defining "System routing logic").

[230] A microsecond is one millionth of a second.

[231] *See* IEX First Response at 3; *see also* Amendment Nos. 2 and 3.

[232] *See* IEX Rule 11.130(a) (noting that members' access to the IEX order book includes the IEX system routing members' routable orders to the order book via the IEX POP); IEX Rule 11.510(c)(1) (stating that "when the System routes all or a portion of a routable order to the Order Book, in accordance with the System routing logic, all inbound and outbound communications (including, without limitation, order messages, cancel messages, and execution report messages found in the Exchange's FIX Specification) traverse an additional POP between the System routing logic and the Order Book"); *see also* IEX Sixth Response at 2 ("Please note that because of the speed bump introduced between the IEX Router and the IEX matching engine, IEX routing members independently choosing to use the IEX Router will experience an additional 350 microseconds of latency as compared to members sending non-routable orders to the IEX matching engine.").

[233] *See* IEX Rule 11.510(c)(1); *see also* IEX Sixth Response at 1–2 (noting that "the IEX Router would receive fill information from the IEX matching engine by way of the speed bump, which would place the IEX Router's ability to receive information from the IEX matching engine on equal terms to an independent broker router").

[234] *See* IEX Rule 11.510(c)(2)(A) (stating that "[t]he System routing logic receives Exchange data products after traversing the POP").

[235] *See* IEX Sixth Response at 1 ("In particular, this redesign eliminates any alleged advantage claimed by the commenters that the Router has over a third party broker routing to IEX.").

[236] *See* IEX Sixth Response at 2 (noting that "the IEX Router would receive IEX quote information (the IEX TOPS feed) over the speed bump, which would place the IEX Router's ability to receive IEX quote information on equal terms to an independent broker router").

[237] *See* IEX Rule 11.230; *see also* IEX Sixth Response at 2. IEX believes that this additional delay should not be to the detriment of a User submitting a routable order, and notes that Users may avoid this additional delay by submitting non-routable orders. *See* IEX Sixth Response at 2. In addition, the trade confirmation report from the IEX matching engine back to the User that submitted the routable order would be subject to a 700 microsecond delay, whereas IEX's proprietary data feed would only be subject to a 350 microsecond delay. *See id.* at 1–2.

[238] *See* Nasdaq Third Letter at 1; Citadel Fifth Letter at 1; Gilliland and Goodlander Letter at 1–2; FIA Second Letter at 2; NYSE Third Letter at 8–9.

[239] *See* NYSE Third Letter at 8–9.

[240] *See* Anonymous March 14 Letter at 2–3.

[241] *See infra* note 243 (citing to prior orders).

exchange's rules.[242] For example, in approving an exchange with an affiliated outbound routing broker, the Commission previously noted that "[a] conflict of interest would arise if the national securities exchange (or an affiliate) provided advantages to its broker-dealer that are not available to other members."[243] The Commission further explained that "advantages, such as greater access to information, improved speed of execution, or enhanced operational capabilities in dealing with the exchange, might constitute unfair discrimination under the Act."[244]

Thus, unique access or preferences that an exchange provides to its outbound order routing function must be taken into account in the analysis of whether an exchange provides outbound routing in a manner consistent with the Act, and in particular, the requirement that an exchange's rules be designed not to permit unfair discrimination and not impose an unnecessary or undue burden on competition.[245]

The Commission believes that the revisions to IEX's outbound routing structure set forth in Amendment Nos. 2, 3, and 4 have eliminated any such improper advantage that may have been provided to IEXS under IEX's initial proposal. The Commission notes that, following these amendments, certain commenters that criticized IEX's initially-proposed outbound routing structure expressed support for IEX's amended outbound routing structure.[246]

The Commission believes that IEX has directly responded to the comments on this point through the changes it proposed in Amendment Nos. 2, 3, and 4. Specifically, by inserting an additional POP/coil delay for routable orders between the IEX routing logic and IEX matching engine, the Commission believes that IEX's ability to provide outbound routing services will now be on substantively comparable terms to a third party routing broker that is a member of IEX. Both the IEX routing logic and a third-party routing broker-dealer would experience 350 microseconds of latency in sending order messages to the IEX matching engine (assuming that the third-party routing broker-dealer sends a non-routable order, which would bypass the IEX routing logic and instead proceed to the IEX matching engine) and 350 microseconds of latency in receiving fill and quote information back from the IEX matching engine. Thus, if the IEX routing logic were to pursue a serial routing strategy, it would do so based on a view of the IEX book that is subject to the POP/coil delay, it would experience the same 350 microsecond latency in the transmission of the order to the IEX book that a routing broker-dealer would experience with its non-routable order, and it would experience the same 350 microsecond latency in waiting to determine what, if any, remainder is left to be routed to away destinations. The Commission believes that these are the same conditions that a third-party routing broker-dealer would experience when pursuing a serial routing strategy involving IEX.

IEX's new router design provides flexibility to its routing functionality to employ either a "spray" approach to routing or a "serial" approach.[247] If the IEX routing logic pursues a "spray" routing approach, which would entail the IEX routing logic simultaneously routing shares to destinations on the IEX routing table, including the IEX book, the Commission believes that IEX's new design will place it on the same footing as a third-party routing broker-dealer choosing to "spray" route to multiple trading destinations, including IEX. Specifically, they both would have a view of the IEX book that is subject to the POP/delay, and thus would be in a similar position with respect to determining how many shares to send to the IEX book as part of the "spray" route. Moreover, the shares that are sent to the IEX book from the IEX routing logic or the third-party routing broker-dealer each would have to traverse the POP/coil before reaching the IEX book.

Thus, under IEX's amended outbound routing rule, IEX's affiliated broker-dealer does not have any structural or informational advantages in its provision of routing services as compared to a third-party broker-dealer member of IEX performing a similar function for itself or others. Thus, the Commission believes that IEX's proposed routing structure, as amended, would not be unfairly discriminatory and would not impose an inappropriate burden on competition.[248]

Accordingly, for the reasons stated above, the Commission believes that the outbound routing functionality of IEX, as amended by Amendment Nos. 2, 3, and 4, and as described in IEX's Sixth Response, is consistent with Section 6(b) of the Act in that it is consistent with the goals of promoting just and equitable principles of trade, removing impediments to and perfecting the mechanism of a free and open market and a national market system, protecting investors and the public interest, and not permitting unfair discrimination between customer, issuers, brokers or dealers.[249]

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[242] *See, e.g.*, Securities Exchange Act Release No. 62716 (Aug. 13, 2010), 75 FR 51295 (August 19, 2010) (granting BATS Y Exchange's request to register as a national securities exchange).

[243] Securities Exchange Act Release No. 44983 (October 25, 2001), 66 FR 55225, 55233 (November 1, 2001) (PCX–00–25) (order approving Archipelago Exchange ("ArcaEx") as the equities trading facility of PCX Equities, Inc.) ("ArcaEx Order"). In the 2001 PCX filing, two commenters expressed concerns regarding ArcaEx's affiliation with the Wave broker-dealer, which operated as the outbound routing broker-dealer for ArcaEx. Specifically, these commenters were concerned that the affiliation between ArcaEx and Wave would be anti-competitive and could create a conflict of interest. *See also supra* note 242, at 51304 (citing to the BATS Y order).

[244] ArcaEx Order, *supra* note 243, at 55233.

[245] If an exchange provides its routing logic with a unique structural advantage, such as preferential access to information from the exchange's order book, that advantage could effectively be passed on to its affiliated routing broker in the form of faster or more informed routing instructions. For example, if an exchange were to provide its routing logic with exclusive access to information that it did not provide broadly to other routing brokers (*e.g.*, to orders resting non-displayed on the exchange's book) that would, on its face, raise concerns under Sections 6(b)(5) and 6(b)(8) of the Act. Such an advantage, if not available on identical terms to routing brokers unaffiliated with the exchange, could unfairly discriminate against those unaffiliated brokers or place an inappropriate burden on their ability to compete with the exchange's outbound routing services, in contravention of the Act. As initially proposed, IEXS would functionally have benefitted from greater access to information compared to other routing brokers because it would have been able to route outbound (based on instructions from the IEX matching engine following an execution (or lack thereof) on IEX) before any other market participant would be in a similar position.

[246] *See, e.g.*, Citadel Fifth Letter; Nasdaq Third Letter; FIA Second Letter; NYSE Third Letter at 8–9. One commenter that was critical of IEX's initially proposed routing structure suggested that Nasdaq's simultaneous routing functionality would be a viable alternative, and noted that it "did not have a negative impact on price discovery or market quality." *See* Hudson River Trading Second Letter at 5. *See also* Securities Exchange Act Release Nos. 67246 (June 25, 2012), 77 FR 38875 (June 29, 2012) (notice of proposed rule change) (notice of Nasdaq simultaneous routing proposal) and 67639 (August 10, 2012), 77 FR 49034 (August 15, 2012) (SR–NASDAQ–2012–071) (order approving proposed rule change).

[247] *See* IEX Sixth Response, at 1 ("Pursuant to the redesign, our Routing logic, when necessary, will have the ability to route to IEX and away exchanges simultaneously utilizing only public information, which will protect the IEX routing member from electronic front running to away exchanges.").

[248] In response to a commenter's questioning whether IEX's differential handling of non-routable orders and routable orders would be unfairly discriminatory or an inappropriate burden on competition (*see* NYSE Third Letter at 8–9), the Commission notes that while a User that sends a routable order to IEX would experience different latencies as compared to a User that sends a non-routable order to IEX, any User may choose to send either kind of order—routable or non-routable—to IEX. Thus, the Commission does not believe that there is any structural advantage in IEX's proposed handling of either kind of order that would be available to certain Users but not to others. In addition, the Commission notes that the design of IEX's system with respect to its handling of routable versus non-routable orders is similar to that of at least one existing exchange. *See* Nasdaq Third Letter at 3 (noting that "if a Nasdaq member does not wish to use Nasdaq's routing functionality, it has the ability to send an order directly to the Nasdaq matching engine, thereby bypassing the exchange system that handles orders designated for routing, and would receive an immediate confirmation of the order's execution on Nasdaq"). *See also id.* at 5 (noting that "[u]sing Nasdaq's order management system is optional, and members opting against using Nasdaq's OMS are not disadvantaged in any way").

7. Protected Quote Status

In light of the POP/coil delay, the issue of whether IEX would operate as an automated trading center, in compliance with Rule 600(b)(4) of Regulation NMS,[250] such that its quotations would be "automated" under Rule 600(b)(3) and thus "protected" under Rule 611 of Regulation NMS (the "Order Protection Rule" or "Trade-Through Rule"),[251] attracted considerable attention among commenters. Specifically, several commenters questioned whether IEX's operation of the POP/coil delay would be consistent with either the Order Protection Rule or the intent behind the Rule.[252] Commenters mainly assert that the 350 microsecond latency caused by the POP and coil calls into question whether IEX quotations would be "automated," and therefore whether they can be "protected," under Regulation NMS.[253]

As noted above, according to IEX, all *incoming* messages (*e.g.,* orders to buy or sell and any modification to a previously sent open order) from any User would traverse the proposed POP/coil delay.[254] In addition, all *outbound* messages from IEX back to a User (*e.g.,* confirmations of an execution that occurred on IEX) would pass through the same route in reverse.[255] IEX's direct proprietary market data feed, which is an optional data feed that IEX would make available to subscribers, also would traverse the coil before exiting at the POP.[256] As a result, a non-routable immediate-or-cancel ("IOC") order, which is a type of order that IEX would permit Users to send to the IEX system, would traverse the proposed POP/coil (and its attendant 350 microsecond delay) before arriving at the IEX system and potentially executing against a displayed quotation on IEX.[257] Likewise, the response from the IEX system to the User indicating the action taken by the IEX system with respect to such IOC order also would traverse the POP/coil and experience a 350 microsecond delay, for a cumulative inbound and outbound intentional delay imposed on a non-routable order of 700 microseconds.[258]

Several commenters asserted that this 700 microsecond delay would not be *de minimis* or otherwise consistent with the Act and the rules thereunder. Some believed that if IEX's best bid and best offer were protected quotations in light of the latency attendant to IEX's POP/coil structure, including the fact that IEX's proprietary market data feed would be subject to such latency as it leaves IEX, it would be detrimental to the market.[259] Some commenters asserted that if IEX's quotation were protected, it would negatively affect the accuracy of the NBBO and the price discovery process, and could lead to market instability.[260] Others were concerned that it would lead to confusion among market participants, and cause a higher incidence of locked or crossed markets.[261] Some commenters contended that orders routed to IEX would experience lower fill rates and inferior executions because routed orders might miss out on better quotes on other markets if they need to route to a stale quote on IEX that had already traded but that fact has not yet been communicated through IEX's proprietary data.[262] In addition, some commenters argued that resting orders, including pegged orders, on away markets could be mispriced, and potentially executed against at a stale price, due to the fact that outgoing proprietary market data from IEX would be subject to the POP/coil latency.[263]

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[249] *See* 15 U.S.C. 78f(b)(5).

[250] 17 CFR 242.600(b)(4).

[251] 17 CFR 242.611. Rule 611(a)(1) requires a trading center to establish, maintain and enforce written policies and procedures that are reasonably designed to prevent trade-throughs on the trading center of protection quotations. 17 CFR 242.611(a)(1).

[252] *See* NYSE First Letter at 5; BATS First Letter at 3; FIA First Letter at 2; Nasdaq First Letter at 2; Citadel First Letter at 3. *See also* Gibson Dunn Letter at 6–7.

[253] *See* BATS First Letter at 2–4; FIA First Letter at 2; NYSE First Letter at 5–7; Nasdaq First Letter at 2; Citadel First Letter at 2–4. Commenters critical of IEX's proposed design cite to language from the Regulation NMS Adopting Release where the Commission elaborated on what it means for a quotation to be "automated," including an interpretation that the term "immediate," as it relates to the definition of an automated quotation, "precludes any coding of automated systems or *other type of intentional device that would delay the action taken* with respect to a quotation" (emphasis added). *See* BATS First Letter at 3; FIA First Letter at 2; Citadel First Letter at 3; Citadel Second Letter at 3; *see also* Securities Exchange Act Release No. 51808 (June 9, 2005) 70 FR 37496, 37534 (June 29, 2005) ("Regulation NMS Adopting Release"). Based on this language, the commenters contend that IEX's quotation cannot be considered automated, or at least question whether it can be so considered. Several commenters urged the Commission not to decide this question in the context of IEX's Form 1. *See, e.g.,* Citadel Second Letter at 4; Nasdaq Second Letter at 1–4; Direct Match Letter at 2–4; Scott Letter. One commenter urged the Commission, should it disagree with the contention that IEX's quotation cannot be protected, to explain its reasoning in a rulemaking proceeding or exemptive order that is subject to public vetting. *See* Citadel Second Letter at 4. Other commenters urged the Commission to articulate clear standards regarding what constitutes a permissible access delay. *See* BATS First Letter at 3–4, 6; T. Rowe Price Letter at 2; Jon D. Letter. One of these commenters supported an interpretation of the definition of an automated quotation that would include the delay resulting from IEX's POP/coil, but further urged the Commission to articulate clear regulatory standards that would be applicable to all trading venues and market participants. *See* BATS Second Letter at 2. Other commenters offered support for IEX's proposed access delay, and challenged the assertion that IEX's quotation would not meet the definition of "automated quotation" under Regulation NMS. *See, e.g.,* Leuchtkafer First Letter at 1–2; Leuchtkafer Second Letter at 1–2; Verret Letter at 4; Franklin Templeton Letter at 2; Upson Letter at 2. IEX asserted that the language of the Order Protection Rule and the Regulation NMS Adopting Release, when considered in light of the context in which the Order Protection Rule was adopted, do not compel the conclusion that IEX's quotes should be considered "manual quotations" instead of "automated quotations." *See* IEX First Response at 5–7; IEX Second Response at 4; IEX Third Response at 1–3.

[254] *See* IEX First Response at 3–4; *see also* IEX Rule 11.510.

[255] *See* IEX Rule 11.510.

[256] *See id.*

[257] IEX has designed its rules relating to orders, modifiers, and order execution to comply with the requirements of Regulation NMS, including Rule 600(b)(3) in particular by providing an immediate-or-cancel functionality. *See* IEX Rules 11.190 and 11.230; *see also* 17 CFR 242.600(b)(3). IEX permits immediate-or-cancel orders to be non-routable when designated as "IEX Only," and thus unexecuted portions of immediate-or-cancel orders designated as such would be canceled without being routed elsewhere, in accordance with Rule 600(b)(3)(iii). *See* IEX Rule 11.190; *see also* 17 CFR 242.600(b)(3)(iii). These proposed rules include accepting orders marked as intermarket sweep orders, which will allow orders so designated to be automatically matched and executed without reference to Protected Quotations at other trading centers, and routing orders marked as intermarket sweep orders by a User to a specific trading center for execution. *See* IEX Rule 11.190(b)(12); *see also* 17 CFR 242.600(b)(3) and 242.611.

[258] *See* IEX Rule 11.510; *see also* IEX First Response at 3. Outbound transaction and quote messages from IEX to the applicable securities information processor ("SIP") would *not* pass through the POP/coil, but instead would be sent directly from the IEX system to the SIP processor without an intentional delay. *See* IEX Rule 11.510(c); *see also* IEX First Response at 3–4.

[259] *See, e.g.,* BATS First Letter at 3; Nasdaq First Letter at 3; FIA First Letter at 3; Citadel First Letter at 4–5; NYSE First Letter at 7–9; Scott Letter; Anonymous December 5 Letter at 2; Hudson River Trading First Letter at 6; PDQ Enterprises Letter at 1–2. *See also* Gibson Dunn Letter at 7.

[260] *See* BATS First Letter at 3; PDQ Enterprises Letter at 1–2 (arguing that because of IEX's POP/coil delay, "its quotes may not be truly actionable on an alarmingly regular basis" and that, if other exchanges adopt access delays of their own, it will lead to order routers "chasing ghost quotes through numerous speed bumps" and, as a result, "price discovery chaos"); Hudson River Trading First Letter at 7 (predicting that other exchanges will seek delays of their own, which would increase market structure complexity and, "during periods of high volatility, several quotes may be intentionally delayed, clouding the view of the NBBO and leading to greater uncertainty for market participants that could contribute to market instability"); Citadel First Letter at 5; *see also* Scott Letter ("While the changes proposed by IEX could potentially be positive for IEX and its owners, the changes accompanying the approach could negatively impact an investors' ability to execute a trade at the best price, the centerpiece of our national market system.").

[261] *See* Nasdaq First Letter at 3; FIA First Letter at 3; Citadel First Letter at 4–5.

Other commenters did not believe that protecting IEX's quotations despite IEX's POP/coil would have a detrimental impact on market quality,[264] and noted that there is latency associated with the transmission of orders to protected quotations at existing market venues—and in some cases, those latencies are greater than that associated with transmitting orders to IEX even factoring in the proposed POP/coil delay.[265] One commenter observed that the 350 microsecond POP/coil delay is "not much more than the normal latency that all trading platforms impose," and that an exchange could achieve the same delay by "locat[ing] its primary data center 65 or more miles away from the other exchange data centers." [266] Another commenter did not find the proposed POP/coil delay "particularly problematic, as the time gap is minimal, and (even including the speed bump) IEX matches orders faster than a number of other markets." [267] Another commenter contended that IEX's POP/coil delay will have little impact on the NBBO calculations of the consolidated tape.[268]

In response to commenters that argued that the POP/coil delay would negatively affect market transparency, degrade the NBBO, or cloud price discovery, the Commission notes that Rule 600(b)(3)(v) requires trading centers to immediately update their displayed quotations to reflect material changes. Market participants today already experience very short delays in receiving updates to displayed quotations, as a result of geographic and technological latencies, similar to those experienced when accessing protected quotations. Indeed, the NBBO is an amalgamation of individual protected quotations from different markets located in different places, and is already subject to geographic, network, computational, and other technological latencies.[269] For any market participant that chooses to use exchange proprietary data feeds, including IEX's feed with its attendant 350 microsecond one-way delay, and calculate the NBBO for itself, they will not experience an unprecedented delay in receiving IEX's data because the 350 microsecond delay on IEX's data is well within the range of geographic and technological latencies that market participants experience today. Thus, latency to and from IEX will be comparable to—and even less than—delays attributable to other markets that currently are included in the NBBO.[270] For this reason, the Commission does not believe the introduction of a small intentional delay like the POP/coil delay will impair market transparency, lead to greater incidences of locked or crossed markets, or materially impact pegged orders on away markets.

In addition, the Commission published notice of a proposed interpretation regarding the permissibility of intentional access delays.[271] Today, the Commission is issuing a final interpretation that, when determining whether a trading center maintains an "automated quotation" for purposes of Rule 611 of Regulation NMS, the term "immediate" in Rule 600(b)(3) precludes any coding of automated systems or other type of intentional device that would delay the action taken with respect to a quotation unless such delay is *de minimis—i.e.,* so short as to not frustrate the purposes of Rule 611 by impairing fair and efficient access to an exchange's quotations.[272] In accordance with that interpretation and the Commission's findings, discussed above, that the application of IEX's POP/coil delay is not unfairly discriminatory and is otherwise consistent with the Act, the Commission does not believe that IEX's POP/coil delay precludes IEX from maintaining an automated quotation. Because the delay imposed by IEX's POP/coil is well within geographic and technological latencies experienced today that do not impair fair and efficient access to an exchange's quotations or otherwise frustrate the objectives of Rule 611, the Commission believes that such intentional delay will not frustrate the purposes of Rule 611 by impairing fair and efficient access to IEX's quotations. Accordingly, the Commission finds that an intentional 700 microsecond delay is de minimis and thus IEX can maintain a protected quotation.[273]

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[262] *See* FIA First Letter at 3; Citadel First Letter at 4, 9; Citadel Fifth Letter at 2–4; PDQ Enterprises Letter at 1–2; Hudson River Trading First Letter at 5; Hudson River Trading Second Letter at 2–4.

[263] *See* NYSE First Letter at 7–9; Citadel First Letter at 5; FIA First Letter at 4; Hudson River Trading First Letter at 6; Anonymous December 5 Letter at 2. Some of these commenters contended that this would lead to the development of order types on other markets that are designed to bypass IEX protected quotations. *See* NYSE First Letter at 8 n.16; FIA First Letter at 4; *see also* Gibson Dunn Letter at 7 (expressing concern that intentional delays such as that proposed by IEX might "open the floodgates to a new wave of complex order types"). Further, one commenter expressed concern that the POP/coil delay could be exploited for manipulative trading purposes. *See* Instinet Letter at 1 (expressing concern that an access delay might be used to "place[] into the public data stream materially unexecutable quotes that persist for, on order, one millisecond"). The Commission believes there is no basis to conclude that concerns regarding manipulative and predatory quoting behavior should be more pronounced on IEX due to the POP/coil delay, than with respect to other exchanges. While the commenter discusses the hypothetical submission of quotes to IEX that are cancelled before any other market participant could react to them, but that linger in the public market data stream for longer durations because of the POP/coil delay on outbound proprietary data, the Commission notes that such quoting behavior, to the extent it constitutes manipulative trading behavior, would be prohibited by the federal securities laws and rules, including Section 10(b) of the Act and Rule 10b–5 thereunder, as well as exchange rules and FINRA rules. The Commission also notes that, in addition to IEX's surveillance procedures, and in addition to IEX's rules prohibiting certain trading practices (*see* the IEX Rule 10.100 series), IEX's rules, as amended, include proposed Rule 10.270, which specifically prohibits disruptive quoting and trading activity on IEX, as well as proposed Rule 9.217, which sets forth an expedited suspension proceeding for alleged violations of Rule 10.270. *See* Amendment No. 4 to IEX's Form 1. The Commission believes that IEX's rules are appropriately designed to prevent and detect quoting behavior of the sort that the commenter is concerned about, as well as, generally, to prevent fraudulent and manipulative acts and practices in accordance with Section 6(b)(5) of the Act. IEX, like all registered national securities exchanges, must comply with the Act and the rules thereunder, and its own rules, and (subject to the provisions of Section 17(d) and the rules thereunder), absent reasonable justification or excuse, enforce compliance with such provisions by its members and persons associated with its members. *See* 15 U.S.C. 78s(g).

[264] *See* Chen & Foley Letter at 5 ("Based on our empirical analysis of Alpha's speed bump in Canada, we believe that IEX's application will not result in detrimental impacts on overall market quality in the United States.").

[265] *See, e.g.,* BATS First Letter at 4; BATS Second Letter at 2–3; Healthy Markets Letter at 4; Angel Letter at 2; Kim Letter; Mannheim Letter; Wilcox Letter. Because the POP/coil delay is not variable, market participants should be able to account for it when routing as they could any other known latency. *See, e.g.,* Chen & Foley Letter at 4 ("The fixed nature of IEX's inbound speed bump enables individual marketable orders from a smart order router spray to be timed to arrive at IEX's speed bump point-of-presence 350 microseconds prior to arrival at other markets, minimizing any potential for information leakage."); Jones C Letter at 4 ("[M]arket participants may change their order submission behavior to substantially blunt IEX's pegged order repricing scheme . . . [by] sending the order to IEX so that it arrives 350 microseconds earlier than it arrives at other venues."). As noted above, in the Jones C Letter, the commenter attempted to quantify the purported cost that certain market participants would incur when IEX pegged orders "fade" before they can be accessed. *See supra* note 214. The Commission believes that market participants who adjust their routing strategies to account for IEX's access delay (which the commenter acknowledged market participants may do) should be able to mitigate the "fade" that they encounter when routing orders to IEX by calibrating the timing of their routed orders so that the orders destined for IEX arrive there 350 microseconds before the orders sent to other venues.

[266] Angel Letter at 3; *see also* Abel/Noser Letter at 2.

[267] Tabb Letter at 1. *See also* Jones C Letter at 2 (noting that "from an economic point of view the 350-microsecond delay [proposed by IEX] per se should not be a particular cause for concern, as it is well within the bounds of the existing, geographically dispersed National Market System, and does not seem likely to contribute substantially to a phantom liquidity problem").

[268] *See* Upson Letter at 1.

[269] *See* Final Interpretation, *supra* note 13.

[270] *See* Healthy Markets Letter at 4 (noting that "[t]he NBBO already includes quotes with varied degrees of time lag" and that the length of IEX's coiled cable "is far less than the distance between NY and Chicago, and is remarkably similar to the distance between Carteret and Mahwah (36 miles)"). *See also* IEX First Response at 6 (stating that "the amount of latency imposed by the POP is less than or not materially different than that currently involved in reaching various exchanges based on geographic factors," and referring, by way of example, to the geographic distance that an order from the Chicago Stock Exchange's Secaucus, New Jersey data center must physically traverse before reaching the Chicago Stock Exchange's trading system in Chicago); *see also id.* at 9–10 (noting that the POP/coil latency is shorter than the latency associated with protected quotations published through FINRA's Alternative Display Facility and the National Stock Exchange's former order delivery product); IEX Second Response at 11 (noting that the distance between Nasdaq's Carteret facility and NYSE's Mahwah facility is 42.8 miles (compared to the IEX coil's approximately 38 mile equivalent)); IEX Third Response at 2. Other commenters similarly understood that the POP/coil latency is comparable to or shorter than natural and geographic latencies in today's market. *See* Angel Letter at 2; BATS First Letter at 4; BATS Second Letter at 2–3; Kim Letter; Mannheim Letter; T. Rowe Price Letter at 2–3; Wilcox Letter. Two commenters specifically suggested that such a delay would be inconsequential or *de minimis*. *See* Angel Letter at 3; Abel/Noser Letter at 2.

8. Market Participants Required To Treat IEX's Quotations as Protected

Consequently, IEX is a trading center whose quotations can be "automated quotations" under Rule 600(b)(3). In turn, IEX is designed to be an "automated trading center" under Rule 600(b)(4) whose best-priced, displayed quotation would be a "protected quotation" under Rules 600(b)(57) and 600(b)(58), and for purposes of Rule 611.[274]

As a result, following the issuance of this order and IEX having met the conditions to begin operating as an automated trading center in a particular symbol, market participants will be required to have reasonably designed policies and procedures to treat IEX's best bid and best offer in such symbol as a protected quotation.[275] At the same time, to meet their regulatory responsibilities under Rule 611(a) of Regulation NMS, market participants must have sufficient notice of new Protected Quotations, as well as all necessary information (such as final technical specifications).[276] The Commission believes that it would be a reasonable policy and procedure under Rule 611(a) to require that industry participants begin treating IEX's best bid and best offer as a Protected Quotation as soon as possible but no later than 90 days after the date of this order, or such later date as IEX begins operation as a national securities exchange. The Commission notes that it has taken the same position with other new equities exchanges.[277]

D. Discipline and Oversight of Members

As noted above, one prerequisite for the Commission's grant of an exchange's application for registration is that a proposed exchange must be so organized and have the capacity to be able to carry out the purposes of the Act.[278] Specifically, an exchange must be able to enforce compliance by its members and persons associated with its members with federal securities laws and rules thereunder and the rules of the exchange.[279] As also noted above, pursuant to the Regulatory Contract, FINRA will perform many of the initial disciplinary processes on behalf of IEX.[280] For example, FINRA will investigate potential securities laws violations, issue complaints, and conduct hearings pursuant to IEX rules. Appeals from disciplinary decisions will be heard by the IEX Appeals Committee[281] and the IEX Appeals Committee's decision shall be final.[282] In addition, the Exchange Board may on its own initiative order review of a disciplinary decision.[283]

The IEX Amended and Restated Operating Agreement and IEX rules provide that the Exchange has disciplinary jurisdiction over its members so that it can enforce its members' compliance with its rules and the federal securities laws and rules.[284] The Exchange's rules also permit it to sanction members for violations of its rules and violations of the federal securities laws and rules by, among other things, expelling or suspending members, limiting members' activities, functions, or operations, fining or censuring members, or suspending or barring a person from being associated with a member, or any other fitting sanction.[285] IEX's rules also provide for the imposition of fines for certain minor rule violations in lieu of commencing disciplinary proceedings.[286]

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[271] *See* Securities Exchange Act Release No. 77407 (March 18, 2016), 81 FR 15660 (March 24, 2016) (S7–03–16) ("Notice of Proposed Interpretation"). In particular, the Commission noted that the POP/coil, because it delays inbound and outbound messages to and from IEX Users, raises a question as to whether, under the interpretation set forth in the Regulation NMS Adopting Release from 2005, IEX will, among other things, "immediately" execute IOC orders under Rule 600(b)(3)(ii), "immediately" transmit a response to an IOC order sender under Rule 600(b)(3)(iv), and "immediately" display information that updates IEX's displayed quotation under Rule 600(b)(3)(v). *See id.; see also* 17 CFR 242.600(b)(3); Regulation NMS Adopting Release, *supra* note 253, at 37504.

[272] *See* Final Interpretation, *supra* note 13. One commenter argued that there is "no evidence of a need for a *de minimis* exception or that planned delays will benefit investors in any meaningful way." Gibson Dunn Letter at 7. This comment pertains mainly to, and is addressed, in the Commission's Final Interpretation, being issued separately today. As stated in the Final Interpretation, the Commission believes that its updated interpretation allowing for *de minimis* intentional access delays in certain circumstances is warranted in light of technological and market developments and is consistent with the purposes of Rule 611.

[273] *See* Final Interpretation, *supra* note 13.

[274] The foregoing discussion of whether IEX can have an automated quote and operate as an automated trading center and therefore receive order protection under Rule 611 focuses on whether the IEX system can "immediately and automatically" execute an order against an IEX quotation within the meaning of the definition of "automated quotation" set forth in Rule 600(b)(3). Rule 600(b)(3) sets forth additional requirements for a quotation to be automated. *See* 17 CFR 242.600(b)(3). Moreover, being capable of displaying "automated quotations," as defined in Rule 600(b)(3), is just one of several requirements that a trading center must satisfy in order to be considered an "automated trading center" under Rule 600(b)(4). *See* 17 CFR 242.600(b)(4). In particular, as summarized above, IEX's trading rules are designed to satisfy the requirements of Rule 600(b)(3) by permitting orders to be marked as "immediate-or-cancel" and providing for immediate and automatic execution of such incoming orders, cancelation of unexecuted portions, transmission of a response to the sender, and updates to its displayed quotation. *See also* IEX Rules 11.230 (Order Execution) and 11.240 (Trade Execution, Reporting, and Dissemination of Quotations). Further, to the extent IEX satisfies the conditions of Rule 600(b)(4), it will operate as an "automated trading center." In such case, IEX can be an automated trading center with automated quotations that are protected under Rule 611.

[275] *See* 17 CFR 242.611(a).

[276] *See* Securities Exchange Act Release No. 53829 (May 18, 2006), 71 FR 30038, 30041 (May 24, 2006) (File No. S7–10–04) (extending the compliance dates for Rule 610 and Rule 611 of Regulation NMS under the Act).

[277] *See, e.g.,* Securities Exchange Act Release Nos. 58375 (August 18, 2008), 73 FR 49498, 49505 (August 21, 2008) (approval of the BATS Exchange) and 61698 (March 12, 2010), 75 FR 13151, 13163 (March 28, 2010) (approval of the EDGA and EDGX exchanges).

[278] *See* 15 U.S.C. 78f(b)(1).

[279] *See id.*

[280] *See supra* notes 120–121 and accompanying text. *See also* IEX Rule 9.001 (noting that IEX and FINRA are parties to a regulatory contract, pursuant to which FINRA will perform certain functions).

[281] *See* IEX Rule 1.160(r).

[282] *See* IEX Rule 9.349(c) (providing, among other things, that if the Exchange Board does not call the disciplinary proceeding for review, the proposed written decision of the IEX Appeals Committee shall become final).

[283] *See* IEX Rule Series 9.350.

[284] *See generally* IEX Amended and Restated Operating Agreement Article X *and* IEX Rules Chapters 8 and 9.

[285] *See* IEX Rule 2.120. *See also* BATS Rule 2.2 (containing a nearly identical provision).

[286] *See* IEX Rule 9.216(b).

Accordingly, as a condition to the operation of IEX, a Minor Rule Violation Plan ("MRVP") filed by IEX under Act Rule 19d–1(c)(2) must be declared effective by the Commission.[287]

The Commission received one comment on this topic, from a commenter that encouraged IEX to adopt a rule similar to BATS Rule 8.17 (Expedited Client Suspension Proceeding) concerning expedited suspension proceedings with respect to alleged violations of IEX's disruptive quoting and trading rule.[288] IEX proposed a substantively similar rule in amendment Nos. 2 and 3.[289] The Commission finds that IEX's Amended and Restated Operating Agreement and rules concerning its disciplinary and oversight programs are consistent with the requirements of Sections 6(b)(6) and 6(b)(7)[290] of the Act in that they provide fair procedures for the disciplining of members and persons associated with members. The Commission further finds that the rules of IEX provide it with the ability to comply, and with the ability to enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the rules of IEX.[291]

E. Listing and Trading on the IEX Exchange[292]

1. Registration Under Section 12(b) of the Act

Once IEX begins operations as a national securities exchange, a security will be considered for listing on IEX only if such security is registered pursuant to Section 12(b) of the Act[293] or such security is subject to an exemption.[294] An issuer may register a security pursuant to Section 12(b) by submitting to IEX a listing application that provides certain required information.[295] The IEX Exchange will review the listing application and, if the listing application is approved, will certify to the Commission that it has approved the security for listing and registration.[296] Registration of the security will become effective thirty days after the receipt of such certification by the Commission or within a shorter period of time as the Commission may determine.[297] Once registration is effective the security is eligible for listing on IEX.[298]

2. Initial and Continuing Listing Standards

The Commission notes that IEX's proposed initial and continuing listing standards for securities to be listed and traded on the IEX Exchange are virtually identical to the current rules for the Nasdaq Global Select Market of The NASDAQ Stock Market.[299] The Commission has previously determined that the initial and continuing listing standards of Nasdaq are consistent with the Act.[300] The Commission believes that IEX's proposed initial and continuing listing standards are consistent with the requirements of the Act. With respect to the standards relating to the listing and delisting of companies, including procedures and prerequisites for initial and continued listing on IEX, obligations of security issuers listed on IEX, as well as rules describing the application and qualification process,[301] IEX's proposed listing rules for securities are virtually identical to those of Nasdaq. With respect to IEX Rule 14.201, which is substantially similar to the analogous rule of NYSE,[302] IEX requires a company seeking the initial listing of one or more classes of securities on IEX to participate in a free confidential pre-application eligibility review to determine whether the company meets the IEX Exchange's listing criteria and, if, upon completion of this review, IEX determines that a company is eligible for listing, IEX will notify that company in writing that it has been cleared to submit an original listing application. The Commission notes that, if, upon completion of this review, the Exchange determines that a company is ineligible for listing, the company may request a review of IEX's determination pursuant to the process set forth in IEX Rule 9.555. In addition, with respect to the standards relating to other securities, including securities of exchange-traded funds and other exchange-traded derivative securities products, the Commission notes that IEX's proposed listing rules are virtually identical to those of Nasdaq.[303]

3. Corporate Governance Standards

The Commission notes that IEX's proposed corporate governance standards in connection with securities to be listed and traded on the IEX Exchange are virtually identical to the current rules of Nasdaq and the NYSE.[304] The Commission has previously determined that the corporate governance standards for listed issuers of Nasdaq and NYSE are consistent with the Act.[305] The Commission finds that IEX's proposed corporate governance listing standards for listed issuers contained in IEX's proposed rules are consistent with Section 6(b)(5) of the Act and satisfy the requirements of Section 10A(m) of the

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[287] 17 CFR 240.19d–1(c)(2).

[288] *See* Instinet Letter at 2.

[289] *See* IEX Rule 9.217.

[290] 15 U.S.C. 78f(b)(6) and (b)(7).

[291] *See* Section 6(b)(1) of the Act, 15 U.S.C. 78f(b)(1).

[292] The Commission did not receive any comments addressing the substance of the listing requirements.

[293] 15 U.S.C. 78*l*(b).

[294] 15 U.S.C. 78*l*(c); IEX Rules 14.202 and 14.203.

[295] 15 U.S.C. 78*l*(b); IEX Rule 14.202. Prior to submitting a listing application to IEX, the issuer would be required to participate in a free confidential pre-application eligibility review, in which the IEX Exchange will determine whether the issuer meets its listing criteria and is eligible to submit a listing application. *See* IEX Rule 14.201.

[296] *See* IEX Rule 14.203(f); 15 U.S.C. 78*l*(d).

[297] 15 U.S.C. 78*l*(d).

[298] *See* IEX Rule 14.203(f); 15 U.S.C. 78l(d).

[299] *See* Nasdaq Rule 5000 series; IEX Rule Chapters 14 and 16. In addition, IEX proposed a Confidential Pre-Application Review of Eligibility for its proposed listing standards, which is based on the equivalent rule of the New York Stock Exchange. *See* IEX Rule 14.201; *see also* NYSE Listed Company Manual Sections 101 and 104 (providing for a free confidential review of the eligibility for listing of any company that requests such a review and provides the necessary documents).

[300] *See* Securities Exchange Act Release No. 53128 (January 13, 2006), 71 FR 3550 (January 23, 2006) (File No. 10–131) (approving the application of Nasdaq to become a registered national securities exchange). *See also* Securities Exchange Act Release No. 66648 (March 23, 2012), 77 FR 19428 (March 30, 2012) (SR–NASDAQ–2012–013) (approving the adoption of listing rules relating to certain derivative securities products).

[301] *See* IEX Rules Chapter 14. IEX Rule 14.201 is the same as the NYSE rule, both of which relate to the confidential pre-application review for eligibility for companies seeking to list on the Exchange. *See* IEX Rule 14.201; *see also* NYSE Listed Company Manual Sections 101 and 104. The Commission notes that, except for IEX Rule 14.201 (which is substantively similar to the rule of NYSE), all other requirements relating to the listing of companies are virtually identical to those of Nasdaq. *See* Nasdaq Rule 5000 series

[302] *See supra* note 301 (referencing IEX Rule 14.201 and NYSE Listed Company Manual Sections 101 and 104).

[303] *See* IEX Rules Chapter 16. *See also* the Nasdaq Rule 5000 series.

[304] *See* Nasdaq Rule 5600 *et seq.*; NYSE Listed Company Manual Section 303A.07(c) (requiring listed companies to maintain an internal audit function to provide management and the audit committee with ongoing assessments of the listed company's risk management processes and system of internal control). *See also* IEX Rule 14.414.

[305] *See* Securities Exchange Act Release No. 53128 (January 13, 2006), 71 FR 3550 (January 23, 2006) (File No. 10–131) (approving the application of Nasdaq to become a registered national securities exchange). The Commission notes that IEX proposed to adopt NYSE's requirement for listed issuers to have an internal audit function. *See* supra note 304 (referencing NYSE Listed Company Manual Section 303A.07(c) and IEX Rule 14.414). *See also* Securities Exchange Act Release No. 48745 (November 4, 2003), 68 FR 64154 (November 12, 2003) (SR–NYSE–2002–33, SR–NASD–2002–77, SR–NASD–2002–80, SR–NASD–2002–138, SR–NASD–2002–139, and SR–NASD–2002–141) (order approving rules relating to corporate governance of listed companies, including rules relating to the internal audit function).

Act and Rule 10A–3 thereunder.[306] The Commission believes that IEX's corporate governance standards for listed issuers are designed to promote independent and objective review and oversight of the accounting and auditing practices of listed issuers and to enhance audit committee independence, authority, and responsibility by implementing the standards set forth in Rule 10A–3.

While IEX does not intend to list securities upon becoming an exchange, it has expressed an intent to do so in the future.[307] The Commission believes that the listings program is an important regulatory function of an exchange, and prior to becoming a primary listing market, the Commission expects IEX to ensure its effective compliance with, and enforcement of, its listing standards on an initial and continued basis.[308]

4. Trading Pursuant to Unlisted Trading Privileges

As an exchange, IEX will be permitted by Section 12(f) of the Act[309] to extend unlisted trading privileges to securities listed and registered on other national securities exchanges, subject to Commission rules. In particular, Rule 12f–5 under the Act requires an exchange that extends unlisted trading privileges to securities to have in effect a rule or rules providing for transactions in the class or type of security to which the exchange extends unlisted trading privileges.[310] The Commission notes that IEX's proposed rules allow it to extend unlisted trading privileges to any security that is an NMS Stock (as defined in Rule 600 of Regulation NMS under the Act) that is listed on another national securities exchange.[311] Accordingly, consistent with Rule 12f–5, IEX's proposed rules provide for transactions in the class or type of security to which the exchange intends to extend unlisted trading privileges.[312] The Commission finds that IEX's proposed rules governing trading pursuant to unlisted trading privileges are therefore consistent with the Act.

F. Section 11(a) of the Act

Section 11(a)(1) of the Act[313] prohibits a member of a national securities exchange from effecting transactions on that exchange for its own account, the account of an associated person, or an account over which it or its associated person exercises investment discretion (collectively, "covered accounts") unless an exception applies. Rule 11a2–2(T) under the Act,[314] known as the "effect versus execute" rule, provides exchange members with an exemption from the Section 11(a)(1) prohibition. Rule 11a2–2(T) permits an exchange member, subject to certain conditions, to effect transactions for covered accounts by arranging for an unaffiliated member to execute transactions on the exchange. To comply with Rule 11a2–2(T)'s conditions, a member: (i) Must transmit the order from off the exchange floor; (ii) may not participate in the execution of the transaction once it has been transmitted to the member performing the execution;[315] (iii) may not be affiliated with the executing member; and (iv) with respect to an account over which the member or an associated person has investment discretion, neither the member nor its associated person may retain any compensation in connection with effecting the transaction except as provided in the Rule.

In a letter to the Commission, IEX requested that the Commission concur with IEX's conclusion that IEX members that enter orders into the IEX trading system satisfy the requirements of Rule 11a2–2(T).[316] For the reasons set forth below, the Commission believes that IEX members entering orders into the IEX trading system would satisfy the requirements of Rule 11a2–2(T).

The Rule's first requirement is that orders for covered accounts be transmitted from off the exchange floor. In the context of automated trading systems, the Commission has found that the off-floor transmission requirement is met if a covered account order is transmitted from a remote location directly to an exchange's floor by electronic means.[317] IEX has represented that the IEX Exchange does not have a physical trading floor, and the IEX trading system will receive orders from members electronically through remote terminals or computer-to-computer interfaces.[318] The Commission believes that the IEX trading system satisfies this off-floor transmission requirement.

Second, the Rule requires that the member and any associated person not participate in the execution of its order after the order has been transmitted. IEX represented that at no time following the submission of an order is a member or an associated person of the member able to acquire control or influence over the result or timing of the order's execution.[319] According to IEX, the execution of a member's order is determined solely by what quotes and orders are present in the system at the time the member submits the order, and the order priority based on the IEX rules.[320] Accordingly, the Commission believes that an IEX member and its associated persons do not participate in the execution of an order submitted to the IEX trading system.[321]

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[306] *See* 15 U.S.C. 78f(b)(5); 15 U.S.C. 78j–1(m); 17 CFR 240.10A–3.

[307] *See* Exhibit N to IEX's Form 1. Upon commencing operations as an exchange, IEX intends to initially trade only securities that have been admitted pursuant to unlisted trading privileges. *See* Exhibit H to IEX's Form 1.

[308] *See* 15 U.S.C. 78s(g)(1).

[309] 15 U.S.C. 78*l*.

[310] *See* 17 CFR 240.12f–5. *See also* Securities Exchange Act Release No. 35737 (April 21, 1995), 60 FR 20891 (April 28, 1995) (File No. S7–4–95) (adopting Rule 12f–5 under the Act).

[311] *See* IEX Rules 11.120 and 16.160. Any such security will be subject to all IEX trading rules applicable to NMS Stocks, unless otherwise noted, including provisions of IEX Rule 11.280 and Chapters 14 and 16 of the IEX Rules. *See* IEX Rule 16.160.

[312] IEX's rules currently do not provide for the trading of options, security futures, or other similar instruments.

[313] 15 U.S.C. 78k(a)(1).

[314] 17 CFR 240.11a2–2(T).

[315] This prohibition also applies to associated persons. The member may, however, participate in clearing and settling the transaction.

[316] *See* Letter from Sophia Lee, General Counsel, IEX, to Brent Fields, Secretary, Commission, dated June 10, 2016 ("IEX 11(a) Letter").

[317] *See, e.g.*, Securities Exchange Act Release Nos. 61419 (January 26, 2010), 75 FR 5157 (February 1, 2010) (SR–BATS–2009–031) (approving BATS options trading); 59154 (December 23, 2008), 73 FR 80468 (December 31, 2008) (SR–BSE–2008–48) (approving equity securities listing and trading on BSE); 57478 (March 12, 2008), 73 FR 14521 (March 18, 2008) (SR–NASDAQ–2007–004 and SR–NASDAQ–2007–080) (approving NOM options trading); 53128 (January 13, 2006), 71 FR 3550 (January 23, 2006) (File No. 10–131) (approving The Nasdaq Stock Market LLC); 44983 (October 25, 2001), 66 FR 55225 (November 1, 2001) (SR–PCX–00–25) (approving Archipelago Exchange); 29237 (May 24, 1991), 56 FR 24853 (May 31, 1991) (SR–NYSE–90–52 and SR–NYSE–90–53) (approving NYSE's Off-Hours Trading Facility); and 15533 (January 29, 1979), 44 FR 6084 (January 31, 1979) ("1979 Release").

[318] *See* IEX 11(a) Letter, *supra* note 316.

[319] *See* IEX 11(a) Letter, *supra* note 316. IEX notes that a member may cancel or modify the order, or modify the instructions for executing the order, after the order has been transmitted, provided that such cancellations or modifications are transmitted from off an exchange floor. The Commission has stated that the non-participation requirement is satisfied under such circumstances so long as such modifications or cancellations are also transmitted from off the floor. *See* Securities Exchange Act Release No. 14563 (March 14, 1978), 43 FR 11542 (March 17, 1978) ("1978 Release") (stating that the "non-participation requirement does not prevent initiating members from canceling or modifying orders (or the instructions pursuant to which the initiating member wishes orders to be executed) after the orders have been transmitted to the executing member, provided that any such instructions are also transmitted from off the floor").

[320] *See* IEX 11(a) Letter, *supra* note 316. The Commission notes that IEX has proposed rules for the registration, obligations, and operation of market makers on the IEX Exchange. IEX has represented that market makers, if any, would submit quotes in the form of orders in their assigned symbols.

Third, Rule 11a2–2(T) requires that the order be executed by an exchange member who is unaffiliated with the member initiating the order. The Commission has stated that this requirement is satisfied when automated exchange facilities, such as the IEX trading system, are used, as long as the design of these systems ensures that members do not possess any special or unique trading advantages in handling their orders after transmitting them to the exchange.[322] IEX has represented that the design of the IEX trading system ensures that no member has any special or unique trading advantage in the handling of its orders after transmitting its orders to IEX.[323] Based on IEX's representation, the Commission believes that the IEX trading system satisfies this requirement.

Fourth, in the case of a transaction effected for an account with respect to which the initiating member or an associated person thereof exercises investment discretion, neither the initiating member nor any associated person thereof may retain any compensation in connection with effecting the transaction, unless the person authorized to transact business for the account has expressly provided otherwise by written contract referring to Section 11(a) of the Act and Rule 11a2–2(T) thereunder.[324] IEX members trading for covered accounts over which they exercise investment discretion must comply with this condition in order to rely on the rule's exemption.[325]

IV. Exemption From Section 19(b) of the Act With Regard to FINRA Rules Incorporated by Reference

IEX Exchange proposes to incorporate by reference certain FINRA rules as IEX rules. Thus, for certain IEX rules, Exchange members will comply with an IEX rule by complying with the FINRA rule referenced.[326] In connection with its proposal to incorporate FINRA rules by reference, IEX Exchange requested, pursuant to Rule 240.0–12,[327] an exemption under Section 36 of the Act from the rule filing requirements of Section 19(b) of the Act for changes to those IEX Exchange rules that are effected solely by virtue of a change to a cross-referenced FINRA rule.[328] IEX Exchange proposes to incorporate by reference categories of rules (rather than individual rules within a category) that are not trading rules. IEX Exchange agrees to provide written notice to its members whenever a proposed rule change to a FINRA rule that is incorporated by reference is proposed and whenever any such proposed change is approved by the Commission or otherwise becomes effective.[329]

Using its authority under Section 36 of the Act,[330] the Commission previously exempted certain SROs from the requirement to file proposed rule changes under Section 19(b) of the Act.[331] The Commission is hereby granting IEX Exchange's request for exemption, pursuant to Section 36 of the Act, from the rule filing requirements of Section 19(b) of the Act with respect to the rules that IEX Exchange proposes to incorporate by reference. This exemption is conditioned upon IEX Exchange providing written notice to its members whenever FINRA proposes to change a rule that IEX Exchange has incorporated by reference. The Commission believes that this exemption is appropriate in the public interest and consistent with the protection of investors because it will promote more efficient use of Commission and SRO resources by avoiding duplicative rule filings based on simultaneous changes to identical rules sought by more than one SRO.

V. Conclusion

It is ordered that the application of IEX Exchange for registration as a national securities exchange be, and it hereby is, granted.

It is furthered ordered that operation of IEX Exchange is conditioned on the satisfaction of the requirements below:

A. *Participation in National Market System Plans*. IEX Exchange must join the CTA Plan, the CQ Plan, the Nasdaq UTP Plan, the Order Execution Quality Disclosure Plan, the Plan to Address Extraordinary Market Volatility, the Plan to Implement a Tick Size Pilot

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[321] *See, e.g.*, Securities Exchange Act Release Nos. 58375 (August 18, 2008), 73 FR 49498, 49505 (August 21, 2008) (approval of the BATS Exchange) and 61698 (March 12, 2010), 75 FR 13151, 13164 (March 28, 2010) (approval of the EDGA and EDGX exchanges).

[322] *See, e.g.*, Securities Exchange Act Release Nos. 58375 (August 18, 2008), 73 FR 49498, 49505 (August 21, 2008) (approval of the BATS Exchange) and 61698 (March 12, 2010), 75 FR 13151, 13164 (March 28, 2010) (approval of the EDGA and EDGX exchanges). In considering the operation of automated execution systems operated by an exchange, the Commission noted that, while there is not an independent executing exchange member, the execution of an order is automatic once it has been transmitted into the system. Because the design of these systems ensures that members do not possess any special or unique trading advantages in handling their orders after transmitting them to the exchange, the Commission has stated that executions obtained through these systems satisfy the independent execution requirement of Rule 11a2–2(T). *See* 1979 Release, *supra* note 317.

[323] *See* IEX 11(a) Letter, *supra* note 316.

[324] *See, e.g.*, Securities Exchange Act Release Nos. 58375 (August 18, 2008), 73 FR 49498, 49505 (August 21, 2008) (approval of the BATS Exchange) and 61698 (March 12, 2010), 75 FR 13151, 13164 (March 28, 2010) (approval of the EDGA and EDGX exchanges). In addition, Rule 11a2–2(T)(d) requires a member or associated person authorized by written contract to retain compensation, in connection with effecting transactions for covered accounts over which such member or associated persons thereof exercises investment discretion, to furnish at least annually to the person authorized to transact business for the account a statement setting forth the total amount of compensation retained by the member or any associated person thereof in connection with effecting transactions for the account during the period covered by the statement. *See* 17 CFR 240.11a2–2(T)(d). *See also* 1978 Release, *supra* note 319 (stating "[t]he contractual and disclosure requirements are designed to assure that accounts electing to permit transaction-related compensation do so only after deciding that such arrangements are suitable to their interests").

[325] IEX represented that it will advise its membership through the issuance of an Information Circular that those members trading for covered accounts over which they exercise investment discretion must comply with this condition in order to rely on the rule's exemption. *See* IEX 11(a) Letter, *supra* note 316.

[326] IEX Exchange proposes to incorporate by reference the 12000 and 13000 Series of the FINRA Manual (Code of Arbitration Procedures for Customer Disputes and Code of Arbitration Procedures for Industry Disputes). *See* IEX Exchange Rule 12.110 (Arbitration). In addition, IEX Exchange proposes to incorporate by reference FINRA Rules 4360 (Fidelity Bonds), 2090 (Know Your Customer), 2111 (Suitability), 2210 (Communications with the Public), 3230 (Telemarketing), 4110 (Capital Requirements), 4120 (Regulatory Notification and Business Curtailment), 4140 (Audit), 4511 (General Requirements), 4512 (Customer Account Information), 4513 (Records of Written Customer Complaints), 3130 (Annual Certification of Compliance and Supervisory Procedures), 5270 (Front Running of Block Transactions), 7430 (Synchronization of Member Business Clocks), 7440 (Recording of Order Information), and 7450 (Order Data Transmission Requirements) and NASD Rule 3050 (Transactions for or by Associated Persons). *See* IEX Exchange Rules 2.240 (Fidelity Bonds), 3.150 (Know Your Customer), 3.170 (Suitability), 3.280 (Communications with Customers and the Public), 3.292 (Telemarketing), 4.110 (Financial Condition), 4.120 (Regulatory Notification and Business Curtailment), 4.140 (Audit), 4.511 (General Requirements), 4.512 (Customer Account Information), 4.513 (Record of Written Customer Complaints), 5.130 (Annual Certification of Compliance and Supervisory Procedures), 10.260 (Front Running of Block Transactions), 11.420(c), (d) and (e) (Order Audit Trail System Requirements), and 5.170 (Transactions for or by Associated Persons), respectively.

[327] *See* 17 CFR 240.0–12.

[328] *See* Letter from Sophia Lee, General Counsel, IEX, to Brent Fields, Secretary, Commission, dated June 13, 2016.

[329] IEX Exchange will provide such notice through a posting on the same Web site location where IEX Exchange posts its own rule filings pursuant to Rule 19b–4 under the Act, within the required time frame. The Web site posting will include a link to the location on the FINRA Web site where FINRA's proposed rule change is posted. *See id.*

[330] 15 U.S.C. 78mm.

[331] *See, e.g.*, BATS Y Exchange Order and MIAX Exchange Order, *supra* note 30; BATS Exchange Order and DirectEdge Exchanges Order, *supra* note 74.

Program, and the Plan Governing the Process of Selecting a Plan Processor and Developing a Plan for the Consolidated Audit Trail.

B. *Intermarket Surveillance Group.* IEX Exchange must join the Intermarket Surveillance Group.

C. *Minor Rule Violation Plan.* A MRVP filed by IEX Exchange under Rule 19d–1(c)(2) must be declared effective by the Commission.[332]

D. *17d–2 Agreement.* An agreement pursuant to Rule 17d–2 [333] between FINRA and IEX Exchange that allocates to FINRA regulatory responsibility for those matters specified above [334] must be approved by the Commission, or IEX Exchange must demonstrate that it independently has the ability to fulfill all of its regulatory obligations.

E. *Participation in Multiparty Rule 17d–2 Plans.* IEX Exchange must become a party to the multiparty Rule 17d–2 agreement concerning the surveillance, investigation, and enforcement of common insider trading rules.

F. *RSA.* IEX Exchange and FINRA must finalize the provisions in the RSA, as described above, that will specify the IEX Exchange and Commission rules for which FINRA will provide certain regulatory functions, or IEX Exchange must demonstrate that it independently has the ability to fulfill all of its regulatory obligations.

It is further ordered, pursuant to Section 36 of the Act,[335] that IEX Exchange shall be exempted from the rule filing requirements of Section 19(b) of the Act with respect to the FINRA rules that IEX proposes to incorporate by reference into IEX Exchange's rules, subject to the conditions specified in this Order.

By the Commission (Chair WHITE and Commissioner STEIN; Commissioner PIWOWAR concurring in part and dissenting with respect to Sections III.C.7 and III.C.8).

Robert W. Errett,

Deputy Secretary.

Exhibit A

Comment Letters Received Regarding Investors' Exchange LLC's Application for Registration as a National Securities Exchange under Section 6 of the Securities Exchange Act of 1934 (File No. 10–222)

Abebe: Letter from Brook Abebe, Dec. 15, 2015.

Abel/Noser: Letter from Eugene Noser, Abel/Noser Corp., Dec. 17, 2015.

Abfall: Letter from Jeffrey D. Abfall, Dec. 10, 2015.

Addy: Letter from Steven Addy, Dec. 11, 2015.

Aesthetic Integration: Letter from Denis A. Ignatovich and Grant Passmore, Co-Founders, Aesthetic Integration Ltd, Nov. 18, 2015.

Agne: Letter from Mike Agne, Dec. 10, 2015.

Ahlfeld: Letter from Ryan Ahlfeld, Dec. 14, 2015.

Akbar: Letter from Imran Akbar, Dec. 14, 2015.

Albert: Letter from Jean Albert, Dec. 15, 2015.

Angel: Letter from James J. Angel, Ph.D., Associate Professor, McDonough School of Business, Georgetown University, Dec. 5, 2015.

Anonymous December 5: Letter from Anonymous, Dec. 5, 2015.

Anonymous December 14: Letter from Anonymous, Dec. 14, 2015.

Anonymous Second December 14: Letter from Anonymous, Dec. 14, 2015.

Anonymous March 14: Letter from Anonymous, Mar. 14, 2016.

Anonymous March 18: Letter from Anonymous, Mar. 18, 2016.

Anonymous June 16: Letter from Anonymous, June 16, 2016.

Arens: Letter from Richard Arens, Dec. 10, 2015.

Armand: Letter from Barry Armand, Dec. 13, 2015.

Arnold: Letter from Lonnie Arnold, Jr., Feb. 2, 2016.

Asset Owners/Investment Managers March 21: Letter from Kevin McCreadie, President and CIO, AGF Investment Inc.; Steve Berexa, Global CIO Equity, Allianz Global Investors; Bryan Thomson, Senior Vice President, Public Equities, British Columbia Investment Management; Faith Ward, Chief Responsible Investment and Risk Officer, Environment Agency Pension Fund; Michelle de Cordova, Director, Corporate Engagement Public Policy, ESG Services, NEI Investments; Oyvind Schanke, CIO Asset Strategies, Norges Bank Investment Management; and David H. Zellner, Chief Investment Officer, Wespath Investment Management, Mar. 21, 2016.

Baggins: Letter from Roger Baggins, Feb. 2, 2016.

Baird: Letter from Ritchie Baird, Jan. 3, 2016.

Baker: Letter from Christopher Baker, Dec. 11, 2015.

Ballestrand: Letter from Bill Ballestrand, Dec. 14, 2015.

Bardini: Letter from Marguerite Bardini, Dec. 14, 2015.

Barry: Letter from Catherine Barry, Jan. 2, 2016.

Barth: Letter from Donald J. Barth, Mar. 4, 2016.

BATS First: Letter from Eric Swanson, EVP and General Counsel, BATS Global Markets, Inc., Nov. 3, 2015.

BATS Second: Letter from Eric Swanson, EVP and General Counsel, BATS Global Markets, Inc., Dec. 20, 2015.

BATS Third: Letter from Eric Swanson, EVP and General Counsel, BATS Global Markets, Inc., Feb. 11, 2016.

Bautista: Letter from Barry Bautista, June 17, 2016.

Ben D.: Letter from Ben D., Mar. 20, 2016.

Benites: Letter from Roger Benites, Dec. 13, 2015.

Bensky: Letter from Jonathan Bensky, Mar. 3, 2016.

Berrizbeitia: Letter from Luis Berrizbeitia, Dec. 14, 2015.

Bilyea: Letter from Robert Bilyea, Dec. 17, 2015.

Bingham: Letter from George B. Bingham, Jan. 8, 2016.

Birch Bay: Letter from Michael Jacejko, Chief Executive Manager, Birch Bay Capital, LLC, Nov. 6, 2015.

Black: Letter from Wade Black, Dec. 17, 2015.

Boatman: Letter from Peter L. Boatman, June 3, 2016.

Bodenstab: Letter from Jeffrey Bodenstab, Dec. 19, 2015.

Bogdan: Letter from Michael Bogdan, Dec. 15, 2015.

Bohr: Letter from Vincent Bohr, Dec. 11, 2015.

Boittiaux: Letter from Thomas Boittiaux, Apr. 22, 2016.

Borbridge: Letter from Harold Borbridge, Dec. 13, 2015.

Bova: Letter from Nicholas M. Bova, Dec. 14, 2015.

Bowcott: Letter from Mike Bowcott, Dec. 9, 2015.

Boyce: Letter from Edward J. Boyce, Dec. 14, 2015.

Brennan: Letter from Michael Brennan, Dec. 16, 2015.

Brenner: Letter from Daniel S. Brenner, Dec. 14, 2015.

Brian S.: Letter from Brian S., Dec. 10, 2015.

Broder: Letter from Michael K. Broder, Jan. 9, 2016.

Bruin: Letter from Eric Bruin, Dec. 16, 2015.

Buckingham: Letter from Mallory Buckingham, Dec. 15, 2015.

Budish: Letter from Eric Budish, Professor of Economics, University of Chicago Booth School of Business, Feb. 5, 2016.

Burger: Letter from Ronald J. Burger, Dec. 19, 2015.

Burgess: Letter from Jack M. Burgess, Dec. 26, 2015.

Byrnes: Letter from Jannette Byrnes, Dec. 13, 2015.

CalSTRS: Letter from Anne Sheehan, Director of Corporate Governance, California State Teachers' Retirement System, Mar. 10, 2016.

Campbell: Letter from Mike Campbell, Dec. 15, 2015.

Cantori: Letter from John Cantori, Dec. 11, 2015.

Capital Group: Letter from Timothy D. Armour, Chairman, The Capital Group Companies, Sep. 29, 2015.

Carper: Letter from Carol Carper, Dec. 27, 2015.

Chen & Foley: Letter from Haoming Chen and Sean Foley, Ph.D., Feb. 24, 2016.

Chesler: Letter from Dan Chesler, Dec. 15, 2015.

Chilson: Letter from Cody J. Chilson, Dec. 10, 2015.

Chung and Jeon: Letter from Michael Chung and Jayoung Jeon, Apr. 10, 2016.

Chung: Letter from Charles Chung, Dec. 15, 2015.

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[332] 17 CFR 240.19d–1(c)(2).

[333] 17 CFR 240.17d–2.

[334] *See supra* notes 134–135 and accompanying text.

[335] 15 U.S.C. 78mm.

Citadel First: Letter from John C. Nagel, Esq., Managing Director and Sr. Deputy General Counsel, Citadel LLC, Nov. 6, 2015.

Citadel Second: Letter from John C. Nagel, Esq., Managing Director and Sr. Deputy General Counsel, Citadel LLC, Nov. 30, 2015.

Citadel Third: Letter from John C. Nagel, Esq., Managing Director and Sr. Deputy General Counsel, Citadel LLC, Dec. 7, 2015.

Citadel Fourth: Letter from John C. Nagel, Esq., Managing Director and Sr. Deputy General Counsel, Citadel LLC, Feb. 23, 2016.

Citadel Fifth: Letter from John C. Nagel, Esq., Managing Director and Sr. Deputy General Counsel, Citadel LLC, Apr. 14, 2016.

Clark B.: Letter from Bruce R. Clark, Ph.D., Dec. 22, 2015.

Clark J. First: Letter from James T. Clark, Jr., Dec. 11, 2015.

Clark J. Second: Letter from James T. Clark, Jr., Dec. 15, 2015.

Clark K.: Letter from Kyle Clark, Dec. 14, 2015.

Cobb: Letter from Jeffrey Cobb, Feb. 13, 2016.

Coe: Letter from Charles R. Coe, Dec. 10, 2015.

Colbert: Letter from Stephen Colbert, Dec. 10, 2015.

Cole: Letter from Rebecca A. Cole, Mar. 20, 2016.

Conklin: Letter from J.J. Conklin, Jan. 5, 2016.

Connolly: Letter from Francis A. Connolly, III, Feb. 2, 2016.

Cook: Letter from Aran Cook, Dec. 14, 2015.

Copelan: Letter from Julie Copelan, Feb. 22, 2016.

Cowen: Letter from Jeffrey M. Solomon, President, Daniel Charney, Managing Director and Head of Equities, and John Cosenza, Managing Director & Head of Electronic Trading, Cowen Group, Inc., Nov. 2, 2015.

Cox First: Letter from Steven M. Cox, Dec. 10, 2015.

Cox Second: Letter from Steven M. Cox, Feb. 2, 2016.

CPMG: Letter from John E. Bateman, Chief Operating Officer, CPMG, Inc., Jan. 5, 2016.

Crespo: Letter from Pablo Crespo, Dec. 10, 2015.

Cull: Letter from Stephanie Cull, Mar. 31, 2016.

Curtin: Letter from Kim Ann Curtin, Jan. 15, 2016.

D.B.: Letter from D.B., Apr. 5, 2016.

Dall: Letter from Cindy Dall, May 11, 2016.

Daniels: Letter from Larry Daniels, Jan. 23, 2016.

Deccristifaro: Letter from Aj Deccristifaro, Feb. 21, 2016.

Delaney: Letter from Stephen W. Delaney, Jan. 1, 2016.

Demos: Letter from Mark Demos, Dec. 16, 2015.

DePoorter: Letter from Walter DePoorter, Dec. 14, 2015.

DeVito: Letter from David J. DeVito, Dec. 10, 2015.

Direct Match: Letter from Jim Greco, CEO, Direct Match, Feb. 24, 2016.

Discepola: Letter from Domenico Discepola, Dec. 11, 2015.

Dole: Letter from William Dole, Dec. 14, 2015.

Doran: Letter from Brendan Doran, Dec. 13, 2015.

Dover: Letter from Roland Dover, Jan. 31, 2016.

Doyle L.: Letter from Larry Doyle , Dec. 14, 2015.

Doyle T.: Letter from Thomas Doyle, Jan. 21, 2016.

Duffy: Letter from Representative Sean P. Duffy, Jan. 21, 2016.

Dukelow: Letter from James S. Dukelow, Jr., Dec. 18, 2015.

Dwork: Letter from Nicholas Dwork, Jan. 27, 2016.

Eric K.: Letter from Eric K., Feb. 16, 2016.

Estate: Letter from Carlos J. Estate, Feb. 28, 2016.

Eustace: Letter from Mark Eustace, Dec. 13, 2015.

Farallon Capital Management: Letter from Andrew J.M. Spokes, Managing Partner, Farallon Capital Management, LLC, Mar. 2, 2016.

Feldscher: Letter from Stephen Feldscher, Mar. 22, 2016.

Ferber: Letter from William Ferber, May 7, 2016.

fi360: Letter from Blaine F. Aikin, Executive Chairman, J. Richard Lynch, Director, and Duane R. Thompson, Senior Policy Analyst, fi360, Inc., Jan. 5, 2016.

FIA First: Letter from Mary Ann Burns, Chief Operating Officer, FIA Principal Traders Group, Nov. 6, 2015.

FIA Second: Letter from Mary Ann Burns, Chief Operating Officer, FIA Principal Traders Group, Mar. 3, 2016.

Fields: Letter from Byron Fields, Jan. 13, 2016.

Filabi: Letter from Azish Filabi, Feb. 3, 2016.

Finley: Letter from Ted Finley, Dec. 14, 2015.

Franklin Templeton Investments: Letter from Madison S. Gulley, EVP, Head of Investment Management Strategic Services, William J. Stephenson IV, SVP, Global Head of Trading, David A. Lewis, SVP, Head of Americas Trading, Benjamin Batory, SVP, Head of U.S. Trading, and Craig S. Tyle, EVP, General Counsel, Franklin Templeton Investments, Feb. 12, 2016.

Franz: Letter from John P. Franz, Feb. 25, 2016.

Froehlich: Letter from Paul Froehlich, Dec. 10, 2015.

Gai: Letter from Robert Gai, Feb. 24, 2016.

Gannon: Letter from James Gannon, Dec. 10, 2015.

Geduld: Letter from E.E. Geduld, Dec. 18, 2015.

Gibbons P.: Letter from Peter Gibbons, Dec. 10, 2015.

Gibbons T.: Letter from Toni Gibbons, Dec. 14, 2015.

Gibson Dunn: Letter from Amir C. Tayrani, Gibson, Dunn & Crutcher LLP, May 19, 2016.

Giguere: Letter from John Giguere, Dec. 14, 2015.

Gilliland and Goodlander: Letter from Jason Gilliland and Maggie Goodlander, Apr. 14, 2016.

Givehchi: Letter from Mehran Givehchi, Dec. 14, 2015.

Glatt: Letter from Alex Glatt, Dec. 14, 2015.

Glennon: Letter from Allan Glennon, Dec. 10, 2015.

Gloy First: Letter from Alexander Gloy, Dec. 10, 2015.

Gloy Second: Letter from Alexander Gloy, Dec. 15, 2015.

Godden: Letter from Daniel Godden, May 31, 2016.

Godonis: Letter from Anthony Godonis, Jan. 28, 2016.

Gold: Letter from James J. Gold, Jan. 9, 2016.

Goldman Sachs: Letter from Paul M. Russo, Managing Director, Equities, Goldman, Sachs & Co., Jan. 12, 2016.

Gordon: Letter from Doug Gordon, Dec. 13, 2015.

Goswami: Letter from Binoo Goswami, Jan. 24, 2016.

Gough: Letter from William S. Gough, Jan. 22, 2016.

Grant: Letter from John Grant, Dec. 13, 2015.

Green: Letter from Jordan Green, Feb. 9, 2016.

Grey: Letter from Richard M. Grey, Feb. 23, 2016.

Guertin: Letter from Robert Guertin, Dec. 11, 2015.

Hall: Letter from Lori Hall, Dec. 13, 2015.

Hamadyk: Letter from Zach Hamadyk, Dec. 19, 2015.

Hamlin: Letter from David Hamlin, Dec. 19, 2015.

Hammermill: Letter from Winston Hammermill, Jan. 22, 2016.

Hammond: Letter from Shaun Hammond, Feb. 21, 2016.

Hand: Letter from David A. Hand, Jan. 27, 2016.

Harbort: Letter from Timothy S. Harbort, Dec. 11, 2015.

Harrison: Letter from Daniel Harrison, Dec. 19, 2015.

Hartley: Letter from Kirk T. Hartley, Dec. 13, 2015.

Hasan: Letter from Nidal Hasan, Dec. 17, 2015.

Hawley: Letter from James Hawley, Dec. 14, 2015.

Haydel: Letter from Christopher J. Haydel, Dec. 11, 2015.

Healthy Markets: Letter from David Lauer, Chairman, Healthy Markets Association, Nov. 6, 2015.

Hedgepath: Letter from Brandon D. Hedgepath, Dec. 11, 2015.

Henderson First: Letter from Hazel Henderson, President and Founder, Ethical Markets Media, Jan. 5, 2016.

Henderson Second: Letter from Hazel Henderson, President and Founder, Ethical Markets Media, Jan. 5, 2016.

Henderson Third: Letter from Hazel Henderson, President and Founder, Ethical Markets Media, Jan. 5, 2016.

Henry: Letter from Patrick Henry, Dec. 19, 2015.

Hibernia: Letter from Emma Hibernia, Dec. 23, 2015.

Hiester: Letter from Christopher Hiester, Dec. 14, 2015.

Holden First: Letter from C.M. Holden, Dec. 13, 2015.

Holden Second: Letter from C.M. Holden, Dec. 14, 2015.

Hollinger: Letter from Nancy Hollinger, Feb. 8, 2016.

Hooper: Letter from Donald C. Hooper, Feb. 22, 2016.

Hovanec First: Letter from Ron Hovanec, Dec. 10, 2015.

Hovanec Second: Letter from Ron Hovanec, Dec. 14, 2015.

Hovanec Third: Letter from Ron Hovanec, Feb. 1, 2016.

Hovanec Fourth: Letter from Ron Hovanec, Feb. 2, 2016.

Hovanec Fifth: Letter from Ron Hovanec, Feb. 25, 2016.

Hovanec Sixth: Letter from Ron Hovanec, Feb. 26, 2016.

Hovanec Seventh: Letter from Ron Hovanec, Mar. 9, 2016.

Howarth: Letter from Charles Howarth, Dec. 10, 2015.

Hudson River Trading First: Letter from Adam Nunes, Head of Business Development, Hudson River Trading LLC, Dec. 4, 2015.

Hudson River Trading Second: Letter from Adam Nunes, Head of Business Development, Hudson River Trading LLC, Jan. 7, 2016.

Huff: Letter from TE Huff, Dec. 15, 2015.

Hunsacker: Letter from Derick Hunsacker, Dec. 11, 2015.

Ianni: Letter from Mike Ianni, Dec. 10, 2015.

Ierardo First: Letter from Mark Ierardo, Dec. 11, 2015.

Ierardo Second: Letter from Mark Ierardo, Dec. 16, 2015.

Instinet: Letter from John Comerford, Executive Managing Director, Global Head of Trading Research, Instinet Holdings Incorporated, Mar. 2, 2016.

Israel: Letter from Representative Steve Israel, June 16, 2016.

Iyer First: Letter from Sree Iyer, Dec. 14, 2015.

Iyer Second: Letter from Sree Iyer, Dec. 20, 2015.

Jacobson: Letter from Cameron Jacobson, Dec. 10, 2015.

James G.: Letter from James G., Dec. 15, 2015.

Janson: Letter from Susan C. Janson, Feb. 4, 2016.

Jefferies: Letter from Jefferies LLC, Jan. 14, 2016.

Jicmon: Letter from Laurentiu I. Jicmon, Ph.D., Dec. 10, 2015.

John J.: Letter from Jacob John, Mar. 17, 2016.

John M.: Letter from Mike John, Dec. 10, 2015.

John P.: Letter from Pramod John, Ph.D., Jan. 29, 2016.

Johnson: Letter from Robert S. Johnson, May 27, 2016.

Jon D.: Letter from Jon D., Dec. 23, 2015.

Jones C.: Letter from Charles M. Jones, Robert W. Lear Professor of Finance and Economics, Columbia Business School, Mar. 2, 2016.

Jones S.: Letter from Sam F. Jones, Dec. 15, 2015.

Joshi: Letter from Kishore A. Joshi, Feb. 5, 2016.

Julos: Letter from Jena A. Julos, Dec. 16, 2015.

Jurgens: Letter from Daniel T. Jurgens, Dec. 10, 2015.

Kaeuper: Letter from Steve Kaeuper, Dec. 19, 2015.

Kara: Letter from Faizal Kara, Dec. 14, 2015.

Katz: Letter from Sondra Katz, Dec. 17, 2015.

Kaye: Letter from Greg Kaye, Dec. 15, 2015.

Kearney: Letter from Michael Kearney, Dec. 14, 2015.

Keblish First: Letter from Peter Keblish, Dec. 9, 2015.

Keblish Second: Letter from Peter Keblish, Dec. 10, 2015.

Keenan: Letter from Chris Keenan, Dec. 18, 2015.

Kelly: Letter from John A. Kelly, Dec. 14, 2015.

Kendall: Letter from Jack R. Kendall, Feb. 4, 2016.

Kennedy First: Letter from Matthew Kennedy, Dec. 10, 2015.

Kennedy Second: Letter from Matthew Kennedy, Dec. 16, 2015.

Kenyon: Letter from Andrew Kenyon, Dec. 14, 2015.

Kiely: Letter from Philip Kiely, Mar. 17, 2016.

Kiessling: Letter from David Kiessling, Dec. 14, 2015.

Kim: Letter from Seong-Han Kim, Ph.D., Dec. 16, 2015.

King First: Letter from Toby King, Dec. 10, 2015.

King Second: Letter from Toby King, Dec. 13, 2015.

King Third: Letter from Toby King, Dec. 31, 2015.

AK Financial Engineering Consultants First: Letter from Abraham Kohen, President, AK Financial Engineering Consultants LLC, Mar. 11, 2016.

AK Financial Engineering Consultants Second: Letter from Abraham Kohen, President, AK Financial Engineering Consultants LLC, Apr. 25, 2016.

Lafayette: Letter from Marcus Lafayette, Dec. 28, 2015.

Lancastle: Letter from Neil M. Lancastle, Senior Lecturer, Accounting and Finance, De Montfort University, Dec. 21, 2015.

Landis Kenesaw: Letter from Kenesaw Landis, Feb. 9, 2016.

Landis Kenneth: Letter from Kenneth Landis, Jan. 1, 2016.

Lantry: Letter from Jackie Lantry, Dec. 14, 2015.

Larson: Letter from Brian C. Larson, Dec. 22, 2015.

Laub: Letter from Craig B. Laub, Dec. 18, 2015.

Lazarus: Letter from Steve Lazarus, Dec. 14, 2015.

Lee F.: Letter from Francis Lee, Jan. 8, 2016.

Lee S.: Letter from Sang Lee, Dec. 10, 2015.

Leeson: Letter from Brock Leeson, Jan. 15, 2016.

Leff: Letter from Bruce Leff, Dec. 26, 2015.

Leino: Letter from Scott Leino, Dec. 29, 2015.

Leuchtkafer First: Letter from R.T. Leuchtkafer, Nov. 20, 2015.

Leuchtkafer Second: Letter from R.T. Leuchtkafer, Feb. 19, 2016.

Levi: Letter from J.D. Levi, Dec. 11, 2015.

Levy: Letter from Steven A. Levy, Dec. 14, 2015.

Lewis: Letter from Michael Lewis, Dec. 12, 2015.

Lewkovich: Letter from Robert Lewkovich, Dec. 14, 2015.

Liquidnet: Letter from Seth Merrin, Founder and CEO, Liquidnet Holdings, Feb. 23, 2016.

Loh: Letter from Roger Loh, Jan. 11, 2016.

Long: Letter from Richard Long, Jan. 15, 2016.

Loomis: Letter from David Loomis, Dec. 16, 2015.

Luce First: Letter from Steve Luce, Dec. 10, 2015.

Luce Second: Letter from Steve Luce, Dec. 12, 2015.

Luoma: Letter from Jeremiah Luoma, Professor of Economics, Finlandia University, Dec. 17, 2015.

Lupinski: Letter from Ryan Lupinski, Jan. 22, 2016.

Lynch: Letter from Representative Stephen F. Lynch, Jan. 8, 2016.

Lysko: Letter from Greg Lysko, May 21, 2016.

Mack: Letter from Carol Mack, Jan. 31, 2016.

MacLeod: Letter from Neil MacLeod, Dec. 17, 2015.

Mannheim: Letter from Lou Mannheim, Dec. 12, 2015.

Manushi First: Letter from Ektrit Manushi, Dec. 24, 2015.

Manushi Second: Letter from Ektrit Manushi, Dec. 29, 2015.

Maqbool: Letter from Massoud Maqbool, May 26, 2016.

Markit First: Letter from David Weisberger, Managing Director, Markit, Dec. 23, 2015.

Markit Second: Letter from David Weisberger, Managing Director, Markit, Feb. 16, 2016.

Marquez: Letter from Thelma Marquez, Dec. 14, 2015.

McCannon: Letter from Xavier McCannon, Dec. 13, 2015.

McCarty: Letter from David McCarty, Dec. 16, 2015.

McCloskey: Letter from Michael J. McCloskey, Esq., Dec. 14, 2015.

McGeer: Letter from Jim McGeer, Dec. 10, 2015.

McGeorge: Letter from Don W. McGeorge, Jan. 4, 2016.

McGowan: Letter from D.S. McGowan, Dec. 10, 2015.

McHugh: Letter from James McHugh, Dec. 17, 2015.

Meeks: Letter from Thomas Meeks, Dec. 10, 2015.

Mehlmann: Letter from Tino Mehlmann, Dec. 10, 2015.

Melin: Letter from Mark H. Melin, Dec. 11, 2015.

Meskill: Letter from Duncan S. Meskill, Dec. 10, 2015.

Metzger: Letter from Andrew Metzger, Mar. 5, 2016.

Meyer: Letter from James Meyer, Dec. 10, 2015.

Michail: Letter from Theocharis Michail, Mar. 7, 2016.

Michel: Letter from Daniel Michel, Feb. 22, 2016.

Millard: Letter from Sean Millard, Dec. 10, 2015.

Milligan: Letter from Christopher Milligan, Dec. 23, 2015.

Modern Markets: Letter from William R. Harts, CEO, Modern Markets Initiative, Dec. 3, 2015.

ModernIR: Letter from Tim Quast , President, ModernNetworks IR LLC, Dec. 7, 2015.

Mollner: Letter from Terry Mollner, Jan. 7, 2016.

Montes: Letter from David J. Montes, Dec. 15, 2015.

Moore: Letter from Dylan Moore, Feb. 28, 2016.

Morgan: Letter from Daniel Morgan, Dec. 15, 2015.

Morris: Letter from Kelly Morris, Apr. 9, 2016.

Morrow: Letter from Benjamin B. Morrow, Jan. 22, 2016.

Moses: Letter from Matt Moses, Dec. 15, 2015.

Mulson: Letter from Danny Mulson, Dec. 15, 2015.

Murphy: Letter from Ann Murphy, Associate Dean, Undergraduate Studies, School of Business, Stevens Institute of Technology, Nov. 6, 2015.

Murray: Letter from Lynn G. Murray, Dec. 29, 2015.

Nagel: Letter from Jeff Nagel, Jan. 8, 2016.

Nakamura: Letter from Tomohiko Nakamura, Feb. 20, 2016.

Nanex First: Letter from Eric S. Hunsader, CEO, Nanex, LLC, Dec. 14, 2015.

Nanex Second: Letter from Eric S. Hunsader, CEO, Nanex, LLC, Jan. 20, 2016.

Nanex Third: Letter from Eric S. Hunsader, CEO, Nanex, LLC, Jan. 25, 2016.

Nasca: Letter from Mark J. Nasca, Jan. 8, 2016.

Nasdaq First: Letter from Joan C. Conley, Senior Vice President and Corporate Secretary, Nasdaq, Inc., Nov. 10, 2015.

Nasdaq Second: Letter from Joan C. Conley, Senior Vice President and Corporate Secretary, Nasdaq, Inc., Jan. 29, 2016.

Nasdaq Third: Letter from Joan C. Conley, Senior Vice President and Corporate Secretary, Nasdaq, Inc., Mar. 16, 2016.

Navari First: Letter from David Navari, Oct. 26, 2015.

Navari Second: Letter from David Navari, Dec. 15, 2015.

Navari Third: Letter from David Navari, Feb. 22, 2016.

Newman: Letter from Lance Newman, Dec. 15, 2015.

Nicholas: Letter from Patrick Nicholas, Apr. 20, 2016.

Nicolas F.: Letter from Nicolas F., Dec. 10, 2015.

Nispel First: Letter from Mark Nispel, Ph.D., Dec. 10, 2015.

Nispel Second: Letter from Mark Nispel, Ph.D, Dec. 14, 2015.

Nixon: Letter from Kasumi Nixon, Jan. 14, 2016.

Noack: Letter from Jared Noack, Dec. 12, 2015.

Noakes: Letter from Nate Noakes, Dec. 15, 2015.

Norges Bank: Letter from Oeyvind G. Schanke, CIO, Asset Strategies, and Simon Emrich, Lead Analyst, Norges Bank Investment Management, Dec. 16, 2015.

Nye: Letter from Joseph J. Nye, Dec. 15, 2015.

NYSE First: Letter from Elizabeth King, General Counsel and Corporate Secretary, New York Stock Exchange, Nov. 12, 2015.

NYSE Second: Letter from Elizabeth King, General Counsel and Corporate Secretary, New York Stock Exchange, Feb. 8, 2016.

NYSE Third: Letter from Elizabeth King, General Counsel & Secretary, New York Stock Exchange, Apr. 18, 2016.

NYSE Fourth: Letter from Elizabeth King, General Counsel & Secretary, New York Stock Exchange, Apr. 27, 2016.

NYSTRS: Letter from Thomas Lee, Executive Director and Chief Investment Officer, and Fred Herrmann, Managing Director of Public Equities, New York State Teachers' Retirement System, Feb. 26, 2016.

O'Connor Letter from Peter O'Connor, Dec. 14, 2015.

O'Malley: Letter from William J. O'Malley, Feb. 5, 2016.

O'Neill: Letter from Robert O'Neill, Dec. 19, 2015.

Odom: Letter from Terry Odom, Feb. 23, 2016.

Olson: Letter from Greg Olson, Dec. 14, 2015.

Oltean: Letter from Ieronim Oltean, Dec. 10, 2015.

Oorjitham: Letter from Jeyan D. Oorjitham, Jan. 30, 2016.

Oppenheimer Funds: Letter from Krishna Memant, Executive Vice President & Chief Investment Officer, George R. Evans, Senior Vice President & Chief Investment Officer of Equities, Keith Spencer, Head of Equity Trading & Senior Vice President, and John Boydell, Manager of Equity Trading & Vice President, OppenheimerFunds, Inc., Nov. 5, 2015.

Papas: Letter from Gregory P. Papas, Dec. 16, 2015.

Park: Letter from Danielle Park, Dec. 10, 2015.

Parks: Letter from Gaelle Parks, Dec. 14, 2015.

Patton C.: Letter from Charles D. Patton, Dec. 14, 2015.

Patton H.D.: Letter from H.D. Patton, Dec. 14, 2015.

Paulikot: Letter from Cameron F. Paulikot, Jan. 12, 2016.

Pavkovic: Letter from Ivan Pavkovic, Dec. 17, 2015.

PDQ Enterprises: Letter from D. Keith Ross, Jr., Chairman and CEO, PDQ Enterprises, LLC, Mar. 16, 2016.

Peck: Letter from Bob Peck, Dec. 30, 2015.

Penkman: Letter from David Penkman, Dec. 14, 2015.

Peppers: Letter from Emmet Peppers, Dec. 10, 2015.

Phelps: Letter from Robert C. Phelps, Dec. 13, 2015.

Philip: Letter from Richard Philip, Ph.D., Lecturer of Finance, University of Sydney, Feb. 9, 2016.

Phillips: Letter from Jeff Phillips, Dec. 17, 2015.

Pierce: Letter from William E. Pierce, Dec. 15, 2015.

Place: Letter from James C. Place, Mar. 16, 2016.

Plant: Letter from Phillip M. Plant, Jan. 8, 2016.

Poots: Letter from Emanuel Poots, Dec. 20, 2015.

Powell: Letter from David R. Powell, Jan. 5, 2016.

Pratt: Letter from William Pratt, Dec. 11, 2015.

Prihodka: Letter from Jonathan M. Prihodka, Feb. 8, 2016.

Prosser G.: Letter from Gabriel Prosser, Feb. 18, 2016.

Prosser W.: Letter from Warren Prosser, Feb. 2, 2016.

Proto: Letter from Paul E. Proto, Feb. 3, 2016.

PSRS/PEERS: Letter from Craig A. Husting, Chief Investment Officer, Public School & Education Employee Retirement Systems of Missouri, Mar. 22, 2016.

Punt: Letter from Ryan L. Punt, Dec. 10, 2015.

Quinlan: Letter from Michael Quinlan, Dec. 13, 2015.

Rademaker: Letter from Jaap Rademaker, Dec. 23, 2015.

Rainbeau: Letter from David Rainbeau, Dec. 10, 2015.

Raju: Letter from Muralidhara Raju, Mar. 1, 2016.

Ramirez First: Letter from Joe Ramirez, Dec. 10, 2015.

Ramirez Second: Letter from Joe Ramirez, Dec. 12, 2015.

Rayner: Letter from Geoff Rayner, Jan. 14, 2016.

Reich: Letter from Kyle Reich, Dec. 11, 2015.

Renterman: Letter from Lemco Renterman, Dec. 14, 2015.

Reynoso: Letter from J.W. Reynoso, Dec. 10, 2015.

Robeson: Letter from Paul Robeson, Jan. 8, 2016.

Romani: Letter from Marina Romani, Mar. 17, 2016.

Romer: Letter from Chris Romer, Mar. 25, 2016.

Rosson: Letter from Joseph C. Rosson, Sr., Dec. 14, 2015.

Rothschild: Letter from Evan Rothschild, Dec. 14, 2015.

Rowley: Letter from Robert P. Rowley, Jan. 5, 2016.

Rundle: Letter from John B. Rundle, Professor of Physics, University of California, Davis, Dec. 31, 2015.

Sadera: Letter from Ernest Sadera, Dec. 16, 2015.

Sakato: Letter from Stacius Sakato, Feb. 15, 2016.

Sanitate: Letter from Frank Sanitate, Dec. 14, 2015.

Sarly: Letter from Alex E. Sarly, Mar. 18, 2016.

Scalici: Letter from Giovanni Scalici, Dec. 11, 2015.

Schlinger: Letter from Charles M. Schlinger, Dec. 15, 2015.

Schroeder M.: Letter from Michael A. Schroeder, Jan. 8, 2016.

Schroeder R. First: Letter from Roy Schroeder, Dec. 11, 2015.

Schroeder R. Second: Letter from Roy Schroeder, Dec. 13, 2015.

Schroeder R. Third: Letter from Roy Schroeder, Dec. 14, 2015.

Schwarz: Letter from Robert Schwarz, Jan. 8, 2016.

Schwefel: Letter from Scott Schwefel, Dec. 11, 2015.

Scott: Letter from Representative David Scott, Feb. 1, 2016.

Seabolt: Letter from Louie H. Seabolt, Feb. 22, 2016.

Seal: Letter from Matthew Seal, Dec. 11, 2015.

Seals: Letter from Devin F. Seals, Dec. 19, 2015.

Secrist: Letter from Kyle Secrist, Dec. 9, 2015.

Sethi: Letter from Rajiv Sethi, Professor of Economics, Barnard College, Columbia University, Jan. 3, 2016.

Sevcik: Letter from Karel Sevcik, Dec. 14, 2015.

Seward: Letter from William Seward, Jan. 3, 2016.

Shamess: Letter from Albie Shamess, Dec. 11, 2015.
Shapurjee: Letter from Rohintan Shapurjee, Feb. 2, 2016.
Shatto First: Letter from Suzanne Shatto, Oct. 7, 2015.
Shatto Second: Letter from Suzanne Shatto, Nov. 16, 2015.
Shatto Third: Letter from Suzanne Shatto, Dec. 7, 2015.
Shatto Fourth: Letter from Suzanne Shatto, Jan. 26, 2016.
Shaw: Letter from Robert Shaw, Jan. 21, 2016.
Sherman: Letter from Representative Brad Sherman, Mar. 7, 2016.
Sillcox: Letter from Robert L. Sillcox, Dec. 14, 2015.
Silva: Letter from Lucas S. Silva, Dec. 14, 2015.
Silver: Letter from David Silver, Feb. 8, 2016.
Simonelis: Letter from Alex Simonelis, Sep. 22, 2015.
Sinclair: Letter from Karen Sinclair, Mar. 15, 2016.
Sjoding: Letter from David W. Sjoding, Mar. 8, 2016.
Slosberg: Letter from Daniel D. Slosberg, Dec. 13, 2015.
Smith C.: Letter from Cale Smith, Jan. 23, 2016.
Smith G.: Letter from Gennifer Smith, Feb. 7, 2016.
Smith J.: Letter from James S. Smith, Dec. 10, 2015.
Smith N.: Letter from Nate Smith, Mar. 10, 2016.
Southeastern: Letter from O. Mason Hawkins, Chairman & CEO, Richard W. Hussey, Principal & COO, Deborah L. Craddock, Principal & Head of Trading, Jeffrey D. Engelberg, Principal & Senior Trader, and W. Douglas Schrank, Principal & Senior Trader, Southeastern Asset Management, Inc., Sep. 30, 2015.
Spear: Letter from Thomas C. Spear, Feb. 2, 2016.
Squires: Letter from Anthony Squires, Dec. 18, 2015.
Stanton: Letter from Carol A. Stanton, Feb. 22, 2016.
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